

EXHIBIT 3

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

- - -

IN RE: ETHICON, INC. : MDL NO. 2327
PELVIC REPAIR SYSTEM, :
PRODUCTS LIABILITY :
LITIGATION :

- - -

THIS DOCUMENT RELATES TO ALL CASES

- - -

June 6, 2013

VOLUME II

- - -

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Continued videotaped 30(b)(6)
deposition of PAUL PARISI taken pursuant to notice,
was held at the law offices of Riker Danzig Scherer
Hyland & Perretti LLP, Headquarters Plaza, One
Speedwell Avenue, Morristown, New Jersey, beginning
at 10:01 a.m., on the above date, before Ann Marie
Mitchell, a Federally Approved Certified Realtime
Reporter, Registered Diplomate Reporter and Notary
Public for the State of New Jersey.

- - -

GOLKOW TECHNOLOGIES, INC.
877.370.3377 ph|917.591.5672 fax
deps@golkow.com

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APPEARANCES:

AYLSTOCK, WITKIN, KREIS & OVERHOLTZ, PLLC
BY: BRYAN F. AYLSTOCK, ESQUIRE
BY: MARY LIU, ESQUIRE
17 East Main Street
Suite 200
Pensacola, Florida 32502
(850) 202-1010
baylstock@awkolaw.com
mliu@awkolaw.com
Representing the Plaintiffs

MAZIE SLATER KATZ & FREEMAN, LLC
BY: ADAM M. SLATER, ESQUIRE
103 Eisenhower Parkway
Second Floor
Roseland, New Jersey 07068
(973) 228-9898
aslater@mskf.net
Representing the Plaintiffs

BUTLER, SNOW, O'MARA, STEVENS & CANNADA, PLLC
BY: MICHAEL L. BROWN, ESQUIRE
1020 Highland Colony Parkway
Suite 1400
Ridgeland, Mississippi 39157
(601) 948-5711
michael.brown@butlersnow.com
Representing Johnson & Johnson and Ethicon
and the Witness

RIKER DANZIG SCHERER HYLAND & PERRETTI LLP
BY: BRETT M. REINA, ESQUIRE
Headquarters Plaza
One Speedwell Avenue
Morristown, New Jersey 07962
(973) 538-0800
breina@riker.com
Representing Johnson & Johnson and Ethicon
and the Witness

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Parisi-1	Force, October 23, 2006, Bates stamped ETH.MESH.00461576	
T-1054	Letter to EWHU Field Sales Force, October 23, 2006, Bates stamped ETH.MESH.00461576	306
T-1055	Article entitled "Transvaginal repair of genital prolapse: preliminary results of a new tension-free vaginal mesh (Prolift technique) -- a case series multicentric study," by B. Fatton, et al., Bates stamped ETH-02358 through ETH-02367	349
T-1056	Gynecare TVT SECUR System Professional Education Program Opportunities, Consider -- Proper Targeting, Course Effectiveness, & Costs, Bates stamped ETH.MESH.05795106	393

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APPEARANCES VIA TELEPHONE:

AYLSTOCK, WITKIN, KREIS & OVERHOLTZ, PLLC
BY: D. RENEE BAGGETT, ESQUIRE
17 East Main Street
Suite 200
Pensacola, Florida 32502
(850) 202-1010
rbaggett@awkolaw.com
Representing the Plaintiffs

HEIDELL, PITTONI, MURPHY & BACH, LLP
BY: NANCY M. MARINI, ESQUIRE
99 Park Avenue
New York, New York 10016
(212) 286-8585
nmarini@hpm.com
Representing Representing Dr. Hines and the Urology Group

CASSIDAY SCHADE LLP
BY: ALEX CAMPOS, ESQUIRE
20 N. Wacker Drive
Suite 1000
Chicago, Illinois 60606
(312) 444-2470
acampos@cassiday.com
Representing Dr. Dorothy Anoina and Women for Women Health Care

PAM MAY LAW FIRM, P.S.C.
BY: NDIDI GBULIE, ESQUIRE
P.O. Box 1439
Pikeville, Kentucky 41502
(606) 432-0400
ngbulie@pammaylaw.com
Representing Altman, McGuire, McClellan & Crum, P.S.C. and Rick A. McClellan

VIDEOTAPE TECHNICIAN:
CHRISTOPHER CAMPBELL

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T-1057 E-mail chain, top one dated May 2011, Bates stamped ETH.MESH.05164815 through ETH.MESH.05164820 402

T-1058 E-mail chain, top one dated Sep 2003, Bates stamped ETH.MESH.03738468 through ETH.MESH.03738470 412

T-1059 PowerPoint, "Ethicon Women's Health & Urology," Bates stamped ETH.MESH.00235558 through ETH.MESH.00235570 415

T-1060 E-mail chain, top one dated February 08, 2011, Bates stamped ETH.MESH.05570260 and ETH.MESH.05570261 423

T-1061 TVT/SUI Professional Education Index and Production Bates Range Chart, 4 pages 430

T-1062 TVT Professional Education Program, Bates stamped ETH.MESH.00156909 through ETH.MESH.00156938 433

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T-1065 E-mail chain, top one dated April 13, 2005, Bates stamped ETH.MESH.05795322 through ETH.MESH.05795324 482

T-1066 KOL Interview: Carl G. Nilsson, Interview: 06.18.08(10-4pm), Bates stamped ETH.MESH.04048515 through ETH.MESH.04048520 502

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<p style="text-align: right;">Page 282</p> <p>1 T-1067 Minutes TVT Secur resolution 516 team, First meeting 1/22/07, 2 Bates stamped ETH.MESH.00528184 and ETH.MESH.00528185 3 T-1068 E-mail dated 30 Apr 2007, Bates 521 4 stamped ETH.MESH.00069114 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p>	<p style="text-align: right;">Page 284</p> <p>1 MS. MARINI: I'm just continuing to 2 preserve the rights I indicated yesterday. We have 3 a court order in the Ferrell vs. Hines matter, which 4 is pending in Connecticut. This deposition is being 5 held open. I'm just continuing to preserve my 6 rights under that court order, and I'm also 7 reserving all objections until the time of trial. 8 Thank you. 9 - - - 10 (A discussion off the record 11 occurred.) 12 - - - 13 MS. GBULIE: So we'll continue our 14 objection about the cross-notice of the video 15 deposition, and we're awaiting a hearing on that 16 matter. Thank you. 17 - - - 18 (A discussion off the record 19 occurred.) 20 - - - 21 THE VIDEOGRAPHER: We are now on the 22 record. My name is Christopher Campbell. I'm a 23 videographer for Golkow Technologies. Today's date 24 is June 6, 2013, and the time is 10:01. This 25 deposition is being held in Morristown, New Jersey,</p>
<p style="text-align: right;">Page 283</p> <p>1 - - - 2 DEPOSITION SUPPORT INDEX 3 - - - 4 5 Direction to Witness Not to Answer 6 Page Line 7 8 9 10 Request for Production of Documents 11 Page Line 12 13 14 15 Stipulations 16 Page Line 17 18 19 20 Question Marked 21 Page Line 22 23 24 25</p>	<p style="text-align: right;">Page 285</p> <p>1 In Re: Pelvic Repair System for the United States 2 District Court, Southern District of West Virginia, 3 Charleston Division. The deponent is Paul Parisi. 4 Counsel will be noted on the stenographic record. 5 The court reporter is Ann Marie Mitchell. The 6 witness has been previously sworn in, and we can now 7 proceed. 8 - - - 9 PAUL PARISI, after having been 10 previously duly sworn, continued to be 11 examined and testified as follows: 12 - - - 13 EXAMINATION 14 - - - 15 BY MR. BROWN: 16 Q. Mr. Parisi, my name is Michael Brown. 17 I represent Ethicon. I'm going to ask you a couple 18 questions now. Okay? 19 A. Yes. 20 Q. Where were you raised? 21 A. Here in New Jersey, Hackensack and 22 Mahwah, New Jersey. 23 Q. Did you go to college? 24 A. Yes, I did. 25 Q. Where?</p>

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<p>1 A. Here in New Jersey, Rutgers 2 University. 3 Q. What's your degree in? 4 MR. SLATER: Objection. It's 5 irrelevant what his -- I'm just kidding. 6 BY MR. BROWN: 7 Q. What's your degree in? 8 A. My degree is in mechanical 9 engineering. 10 Q. Are you a medical doctor? 11 A. No, I'm not. 12 Q. How long have you been at Ethicon? 13 A. It will be 22 years this October. 14 Q. Why did you come to Ethicon? 15 A. I came to Ethicon because I thought I 16 could make a difference in healthcare and providing 17 better care for patients. 18 Q. What is your current job at Ethicon? 19 A. Regional manager of professional -- 20 regional professional education manager. 21 Q. What are your job responsibilities? 22 A. I help to coordinate the education of 23 surgeons by coordinating surgeons to teach other 24 surgeons on our products. 25 Q. What is the purpose of Ethicon's</p>	<p>1 hands-on lab programs. There are what we call 2 preceptorships, where a learning surgeon travels and 3 attends multiple surgical procedures with the 4 teaching surgeon. Additionally, there are 5 proctorships where the teaching surgeon goes and 6 teaches the learning surgeon or observes the 7 learning surgeon in their operating room. 8 Q. Was this type of training provided 9 for the Prolift product? 10 A. If I could amend that previous 11 answer? 12 Q. Sure. 13 A. There are also webcasts, there's 14 online training available as well. 15 Q. Let me restate the question. 16 Was this type of training provided 17 for the Prolift product? 18 A. Yes. 19 Q. And the Prolift+M product? 20 A. Yes. 21 Q. Was this type of training provided 22 for the Prosima product? 23 A. Yes. 24 Q. And what about the TVT products? 25 A. Yes, all of the TVT products.</p>
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<p>1 professional education program? 2 A. The purpose of Ethicon's professional 3 education program is to teach surgeons the use of 4 our products and to provide training hands on and 5 through presentations and lectures and other 6 materials. 7 Q. Now, in your deposition, you were 8 shown multiple professional education, what we call 9 slide decks or PowerPoints. 10 Is that all that Ethicon provides the 11 doctors in professional education? 12 A. No. 13 Q. What else does Ethicon provide these 14 surgeons? 15 A. In addition to the slide decks, we 16 provide the instructions for use, we provide 17 surgical technique documents, we provide procedure 18 DVDs that contain videos, procedure steps, some 19 other materials associated with the procedure. 20 The -- oftentimes, there are clinical articles also 21 provided. 22 Q. If you would, explain the types of 23 professional education programs Ethicon provides. 24 A. Ethicon provides a few different 25 types of professional education programs. There are</p>	<p>1 Q. Who trains the surgeons? 2 A. Surgeons train the surgeons. 3 Q. What is required before a surgeon can 4 become a trainer for the Prolift products? 5 A. There's numerous requirements. The 6 surgeon has to be board certified in urology, 7 urogynecology or gynecology. They have to be one of 8 the thought leaders or well respected in their 9 field. And they have to have experience in using 10 the product safely and effectively. 11 Q. Is that the same requirements for 12 TVT? 13 A. Yes. 14 Q. Who answers the questions regarding 15 the procedure? 16 A. Surgeons answer the questions 17 regarding the procedure. 18 Q. Now, if a surgeon or a trainee 19 attends one of these training events and wants 20 additional training, does Ethicon provide that 21 additional training? 22 A. Absolutely. 23 Q. Can you give me an example of that? 24 A. Yeah. The surgeon who's teaching the 25 procedure would provide their e-mail address and</p>

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<p>1 cell phone and invite the learning surgeons to reach</p> <p>2 them back if they have any additional questions. If</p> <p>3 the learning surgeon misplaced that information,</p> <p>4 they could get that through their representative or</p> <p>5 through the professional education department.</p> <p>6 Q. If a training surgeon goes through a</p> <p>7 preceptorship program where they watch the surgery</p> <p>8 and they want to then have a trainer come and train</p> <p>9 them, would Ethicon provide that additional</p> <p>10 training?</p> <p>11 A. Absolutely.</p> <p>12 Q. Now, if there are complications or a</p> <p>13 physician needs assistance, can he then go back to</p> <p>14 that training surgeon and ask questions?</p> <p>15 A. Absolutely.</p> <p>16 Q. Is that part of the trainer's</p> <p>17 responsibility?</p> <p>18 A. Yes, it is.</p> <p>19 Q. And tell me about that.</p> <p>20 A. The training surgeon would be under</p> <p>21 an agreement with the company that they would not</p> <p>22 only provide education during professional education</p> <p>23 events, but they would be able to be open to</p> <p>24 questions, discussion, be open to, as I said before,</p> <p>25 travel to that doctor's operating room. We made</p>	<p>1 A. This is the criteria for learners of</p> <p>2 the Prolift products.</p> <p>3 Q. Tell me a little bit about some of</p> <p>4 these criteria.</p> <p>5 A. There's numerous things that, in</p> <p>6 addition to, as I stated previously, the surgeon</p> <p>7 would be certified, board certified in gynecologic,</p> <p>8 urologic or urogynecologic surgery. Additionally,</p> <p>9 there were six requirements that were specific to</p> <p>10 the Prolift procedure.</p> <p>11 Would it be helpful if I read those?</p> <p>12 Q. Sure.</p> <p>13 A. The first requirement is that "at</p> <p>14 least 30-50% of their practice is Pelvic Floor</p> <p>15 Repair." The second requirement is they "should be</p> <p>16 doing at least 5 pelvic floor procedures per month</p> <p>17 and treating stage 3 & stage 4 defects." The third</p> <p>18 is that they "use" either an "abdominal or vaginal</p> <p>19 approach to treat pelvic organ prolapse." The</p> <p>20 fourth is that they use "obturator slings." The</p> <p>21 fifth is that they "perform or have performed</p> <p>22 sacrospinous ligament fixations or</p> <p>23 sacrocolpopexies." And the last is that they</p> <p>24 "utilize graft materials in the majority of POP</p> <p>25 cases." And graft materials would be comprehensive</p>
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<p>1 education available in a variety of different ways</p> <p>2 so that the training surgeons had an opportunity to</p> <p>3 access it however they felt it was best suited for</p> <p>4 their needs.</p> <p>5 Q. Are there any educational</p> <p>6 requirements for the surgeons who are being trained?</p> <p>7 A. Yes.</p> <p>8 Q. Did they go to medical school?</p> <p>9 A. Yes.</p> <p>10 Q. Did they have a specialty in any</p> <p>11 area?</p> <p>12 A. Yes. They had specialty with these</p> <p>13 products in gynecology, urogynecology or urology.</p> <p>14 Q. Mr. Parisi, I'm showing you what's</p> <p>15 been marked as Defense Exhibit 1.</p> <p>16 - - -</p> <p>17 (Deposition Exhibit No. D Parisi-1,</p> <p>18 Letter to EWHU Field Sales Force, October</p> <p>19 23, 2006, Bates stamped ETH.MESH.00461576,</p> <p>20 was marked for identification.)</p> <p>21 - - -</p> <p>22 BY MR. BROWN:</p> <p>23 Q. Are you familiar with this document?</p> <p>24 A. Yes, I am.</p> <p>25 Q. What is it?</p>	<p>1 of all types of augments of repair like mesh</p> <p>2 material.</p> <p>3 Q. Now, who develops these training</p> <p>4 materials that we've talked about for these</p> <p>5 surgeons?</p> <p>6 A. Surgeons develop the training</p> <p>7 materials.</p> <p>8 Q. Why is that?</p> <p>9 A. Because we feel that it's important</p> <p>10 that medical information be provided from surgeons</p> <p>11 to be delivered by surgeons to surgeons.</p> <p>12 Q. And why do you, Mr. Parisi, not</p> <p>13 actually develop the content for the professional</p> <p>14 education?</p> <p>15 A. Because I'm not a medical doctor, and</p> <p>16 surgeons have much more in-depth knowledge of</p> <p>17 medical procedures.</p> <p>18 Q. Counsel asked you some very specific</p> <p>19 language regarding complications used in these</p> <p>20 professional education slide decks. Do you remember</p> <p>21 that?</p> <p>22 A. I do, yes.</p> <p>23 Q. When he asked you if those certain</p> <p>24 words were in the slide decks, were you able to</p> <p>25 answer those yes or no?</p>

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<p>1 A. Yes.</p> <p>2 Q. When he asked you words to that</p> <p>3 effect or where complications of a certain severity</p> <p>4 were disclosed, you sometimes deferred to medical</p> <p>5 affairs. Do you remember that?</p> <p>6 A. I do, yes.</p> <p>7 Q. Why did you do that?</p> <p>8 A. Because I felt like I didn't have</p> <p>9 direct knowledge and that those questions would be</p> <p>10 better answered by a medical doctor.</p> <p>11 Q. Why is that? Why should surgeons</p> <p>12 answer those questions?</p> <p>13 A. Because surgeons have years of</p> <p>14 training and in-depth knowledge that comes from</p> <p>15 their training and from their experience operating</p> <p>16 on patients. It's most appropriate to get accurate</p> <p>17 information directly from surgeons teaching other</p> <p>18 surgeons. And that's why we do that.</p> <p>19 Q. Now, I'm showing you a professional</p> <p>20 education slide deck or if you would -- it's</p> <p>21 Exhibit 127.</p> <p>22 A. I have that, thank you.</p> <p>23 Q. Is this the 2005 professional</p> <p>24 education slide deck?</p> <p>25 A. Yes, it is.</p>	<p>1 information. So I object to that.</p> <p>2 MR. BROWN: If you believe it's</p> <p>3 leading, if you just put your objection on the</p> <p>4 record.</p> <p>5 MR. SLATER: So you want me to object</p> <p>6 to every question?</p> <p>7 MR. BROWN: If you believe it's</p> <p>8 leading.</p> <p>9 MR. SLATER: Okay. I object to that</p> <p>10 question as a leading question and inappropriate for</p> <p>11 you to ask the question in that manner of your own</p> <p>12 witness in this context.</p> <p>13 And also, I just want to place one</p> <p>14 other thing on the record.</p> <p>15 Well, actually, I'll save that for</p> <p>16 when it happens.</p> <p>17 BY MR. BROWN:</p> <p>18 Q. If you would look at Exhibit T-1047.</p> <p>19 A. I have that, thank you.</p> <p>20 MR. SLATER: What is T-1047? Is that</p> <p>21 the article?</p> <p>22 MR. BROWN: It is.</p> <p>23 MR. SLATER: That was being miscited?</p> <p>24 BY MR. BROWN:</p> <p>25 Q. Mr. Parisi, if you would, I'm going</p>
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<p>1 Q. And if you would, flip over to the</p> <p>2 TVM retrospective study that discusses postoperative</p> <p>3 complications. It's about halfway through the deck.</p> <p>4 A. Yes, I have that.</p> <p>5 Q. Do you remember counsel asking you</p> <p>6 questions about the vaginal exposures with mesh</p> <p>7 being 25 and that possibly being inconsistent with</p> <p>8 what is in a study by Michel Cosson?</p> <p>9 A. I do remember that.</p> <p>10 MR. SLATER: I object -- for the</p> <p>11 record, I object to all these questions about, do</p> <p>12 you remember counsel asking you this question. I</p> <p>13 think what needs to happen is, because he is your</p> <p>14 witness, you cannot ask any leading questions. And</p> <p>15 I don't think you need to ask the questions in that</p> <p>16 manner in order to elicit information. I think you</p> <p>17 can ask him nonleading questions, and I object to</p> <p>18 any -- I mean, I can object every time you do it or</p> <p>19 you can grant me a standing objection for this</p> <p>20 deposition. I object to any leading question,</p> <p>21 including those where you suggest the entire context</p> <p>22 of what you're getting at, which is I think leading,</p> <p>23 because what you're doing is supplying information</p> <p>24 as you go. I think it would be better if you just</p> <p>25 asked nonleading questions where you asked him for</p>	<p>1 to ask you to look, it's Bates number 2797. You'll</p> <p>2 see that on the bottom right.</p> <p>3 If you'll look on the right column,</p> <p>4 the first paragraph, you'll see "Perioperative</p> <p>5 complications." Do you see that?</p> <p>6 A. I do, yes.</p> <p>7 Q. If you will move down just a little</p> <p>8 bit further to where it says, "The mesh exposure</p> <p>9 complication." Do you see that?</p> <p>10 A. I do, yeah.</p> <p>11 Q. Would you read that sentence.</p> <p>12 A. "The mesh exposure complication was</p> <p>13 observed in 34 patients (12...%)."</p> <p>14 Q. The next part, please.</p> <p>15 A. "However, only 25 patients warranted</p> <p>16 surgery for partial removal of the mesh (9...%)."</p> <p>17 Q. Now, if you look at the slide that</p> <p>18 I'm showing you, which has "TVM Retrospective</p> <p>19 Study," this is on Exhibit 127, that says</p> <p>20 "Postoperative Complications." Do you have that?</p> <p>21 A. Yes, I do. Thank you.</p> <p>22 Q. What does --</p> <p>23 How many patients does it say vaginal</p> <p>24 exposure with mesh had?</p> <p>25 A. It says 25 patients.</p>

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<p>1 Q. And did those require surgical</p> <p>2 partial resection?</p> <p>3 A. Yes. It says very specifically, 25</p> <p>4 patients had vaginal exposure with mesh and required</p> <p>5 partial -- surgical partial resection.</p> <p>6 Q. And, Mr. Parisi, is that consistent</p> <p>7 with the article and information you just read?</p> <p>8 A. Yes, it is.</p> <p>9 Q. Now, if you will, if you will go back</p> <p>10 about three slides, it says, "Defect Type Impacts</p> <p>11 Exposure Rates." Do you see that?</p> <p>12 A. I do, yes.</p> <p>13 Q. How many exposures are identified in</p> <p>14 this slide?</p> <p>15 A. 34.</p> <p>16 Q. And is that consistent with article</p> <p>17 T-1047?</p> <p>18 A. Yes, it is.</p> <p>19 MR. SLATER: Which page of the</p> <p>20 PowerPoint are you on?</p> <p>21 MR. BROWN: "Defect Type Impacts</p> <p>22 Exposure Rates," I think it's about three slides</p> <p>23 after that, the one we were just on. Postoperative</p> <p>24 complications, uterine, technique.</p> <p>25 BY MR. BROWN:</p>	<p>1 hemorrhage or hematoma, surgical intervention.</p> <p>2 Q. Go to the next slide, please.</p> <p>3 What does the next slide indicate to</p> <p>4 you?</p> <p>5 A. "Complications."</p> <p>6 Q. And what are the postoperative</p> <p>7 complications that are identified?</p> <p>8 A. Vaginal adhesion, symptomatic tissue</p> <p>9 contraction, vaginal exposure with mesh and anatomic</p> <p>10 failure.</p> <p>11 Q. Go to the next slide, Mr. Parisi.</p> <p>12 What does that slide indicate?</p> <p>13 A. Another complication, which is the</p> <p>14 exposure rate.</p> <p>15 Q. Go to the next slide, Mr. Parisi.</p> <p>16 What does that slide indicate?</p> <p>17 A. Another complication, which is the</p> <p>18 exposure rate.</p> <p>19 Q. Go to the next slide, Mr. Parisi.</p> <p>20 What does that slide indicate?</p> <p>21 A. Another complication, which is the</p> <p>22 exposure rate.</p> <p>23 Q. Mr. Parisi, I want to direct your</p> <p>24 attention to Exhibit Number 128.</p> <p>25 Mr. Parisi, if you would, I need you</p>
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<p>1 Q. Mr. Parisi, I also want to talk to</p> <p>2 you about this slide deck and being fair and</p> <p>3 balanced.</p> <p>4 What does fair and balanced mean to</p> <p>5 you?</p> <p>6 A. Fair and balanced means that the</p> <p>7 information is accurate and it's complete.</p> <p>8 Q. Mr. Parisi, if you will, I'd like for</p> <p>9 you to flip back about three slides, might be four,</p> <p>10 but it will say "TVM Retrospective Study."</p> <p>11 A. Yes.</p> <p>12 Q. Come back one more, please. It says,</p> <p>13 "Sites: Lille, France." Do you see that?</p> <p>14 A. I do, yes.</p> <p>15 Q. Thank you.</p> <p>16 Is this the retrospective study with</p> <p>17 the 277 patients?</p> <p>18 A. Yes, it is.</p> <p>19 Q. And if you would, on the very next</p> <p>20 slide, if you would flip over, please, what does</p> <p>21 this slide indicate?</p> <p>22 A. "Intraoperative Complications."</p> <p>23 Q. And tell me the complications that</p> <p>24 are listed there.</p> <p>25 A. Rectal injury, bladder injury,</p>	<p>1 to go to the slide, if you'll flip through to</p> <p>2 "Retrospective Study From the Original FRENCH</p> <p>3 Surgical Team."</p> <p>4 A. Can you just tell me approximately --</p> <p>5 Q. You're probably about a third of the</p> <p>6 way through the deck.</p> <p>7 A. Okay, thank you.</p> <p>8 MR. SLATER: What's the title of the</p> <p>9 page?</p> <p>10 MR. BROWN: It's that "Retrospective</p> <p>11 Study From the Original French Surgical Team."</p> <p>12 THE WITNESS: Can I see the page?</p> <p>13 Yes, I have that page. Thank you.</p> <p>14 MR. BROWN: Adam, I'll wait till you</p> <p>15 get there. That's it.</p> <p>16 BY MR. BROWN:</p> <p>17 Q. Mr. Parisi, what does this slide</p> <p>18 indicate? Or just strike that question.</p> <p>19 Would you read the title from this</p> <p>20 slide?</p> <p>21 A. "Retrospective Study From the</p> <p>22 Original French Surgical Team."</p> <p>23 Q. Is this discussing a French study?</p> <p>24 A. Yes, it is.</p> <p>25 Q. If you go to the next page, what does</p>

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<p>1 it indicate?</p> <p>2 A. Complications that were found in that</p> <p>3 study, and it goes on to list a number of</p> <p>4 perioperative, which is during the procedure, and</p> <p>5 postoperative, which is after the procedure.</p> <p>6 Q. And if you'll go to the next slide,</p> <p>7 what's the title of the next slide?</p> <p>8 A. "TVM Mesh Exposure."</p> <p>9 Q. What does this slide indicate?</p> <p>10 A. This indicates the exposure rate that</p> <p>11 was found in the French study.</p> <p>12 Q. And if you look for the third bullet,</p> <p>13 what does the third bullet say?</p> <p>14 A. Those that required intervention in</p> <p>15 the OR, and it lists percentages across a variety of</p> <p>16 different patients that were in the study.</p> <p>17 Q. If you'll go towards the end of the</p> <p>18 slide deck, the title page will say "Complications."</p> <p>19 Tell me when you're there.</p> <p>20 A. Yes.</p> <p>21 Q. Mr. Parisi, if you flip to the next</p> <p>22 page, what does this slide indicate?</p> <p>23 A. "Healing Abnormalities" or exposure</p> <p>24 rate, which is a type of complication.</p> <p>25 Q. If you will skip to the next page,</p>	<p>1 complications, exposures and the number of patients</p> <p>2 and the percentages that those complications were</p> <p>3 experienced in the study.</p> <p>4 Q. Do you remember being asked about</p> <p>5 voiding dysfunction?</p> <p>6 A. I do, yes.</p> <p>7 Q. Is voiding dysfunction identified --</p> <p>8 MR. BROWN: Objection to the form of</p> <p>9 the question. He wasn't asked about voiding</p> <p>10 dysfunction.</p> <p>11 BY MR. BROWN:</p> <p>12 Q. Does this slide indicate voiding</p> <p>13 dysfunction as a potential complication?</p> <p>14 MR. SLATER: Objection, leading.</p> <p>15 THE WITNESS: This slide does</p> <p>16 indicate voiding dysfunction as a potential</p> <p>17 complication.</p> <p>18 BY MR. BROWN:</p> <p>19 Q. If you would as well, let me have you</p> <p>20 on the -- do you see where it says "Complications,"</p> <p>21 the top block?</p> <p>22 A. If I could amend that previous</p> <p>23 answer?</p> <p>24 Q. Uh-huh.</p> <p>25 A. Voiding dysfunction is listed several</p>
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<p>1 two pages over, please. Tell me what this page</p> <p>2 indicates.</p> <p>3 A. "Bleeding," which is a type of</p> <p>4 complication.</p> <p>5 Q. The next page, and the title is</p> <p>6 "Visceral Injury," what does that indicate?</p> <p>7 A. Visceral injury is injury to organs,</p> <p>8 which is a type of complication.</p> <p>9 Q. Mr. Parisi, if you'll go to the next</p> <p>10 page, please.</p> <p>11 You received questions with regard to</p> <p>12 pain or dyspareunia. Do you remember that?</p> <p>13 A. I do, yes.</p> <p>14 Q. What does this slide indicate?</p> <p>15 A. This indicates complications of pain</p> <p>16 and dyspareunia and how to avoid those</p> <p>17 complications.</p> <p>18 Q. Turn to the next page, please.</p> <p>19 Can you read the title, please?</p> <p>20 A. "GYNECARE PROLIFT System: Early</p> <p>21 Outcome Data."</p> <p>22 Q. Mr. Parisi, what is this slide</p> <p>23 depicting?</p> <p>24 A. This depicts a detailed summary of</p> <p>25 the clinical study which indicates the</p>	<p>1 times on this slide.</p> <p>2 Q. Let me ask you, if you would, do you</p> <p>3 see the blocks and do you see the "Complications"</p> <p>4 block?</p> <p>5 A. Yes, I do.</p> <p>6 MR. SLATER: Objection.</p> <p>7 BY MR. BROWN:</p> <p>8 Q. If you would look down two blocks</p> <p>9 below that, read the three complications that are</p> <p>10 indicated there.</p> <p>11 A. "Cystotomy."</p> <p>12 MR. SLATER: Objection.</p> <p>13 THE WITNESS: "Hematoma" and "voiding</p> <p>14 dysfunction."</p> <p>15 MR. BROWN: Thank you, Mr. Parisi.</p> <p>16 No further questions.</p> <p>17 MR. SLATER: That's your direct?</p> <p>18 MR. BROWN: That's it.</p> <p>19 MR. SLATER: Okay. I'm going to</p> <p>20 follow up now if you want to take a second to get</p> <p>21 situated.</p> <p>22 - - -</p> <p>23 EXAMINATION</p> <p>24 - - -</p> <p>25 BY MR. SLATER:</p>

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<p>1 Q. Mr. Parisi, let's start with Exhibit 2 D-1, which -- what I'd also like to do is put a date 3 on it -- 4 A. Yeah, this doesn't say D-1 on it. It 5 says -- 6 Q. It says "D-Parisi." What I'm going 7 to do is I'm going to mark this exhibit as Exhibit 8 T-1054, because we neglected to use it yesterday and 9 we really wanted to, so I want to thank counsel for 10 getting it in here for us. 11 - - - 12 (Deposition Exhibit No. T-1054, 13 Letter to EWHU Field Sales Force, October 14 23, 2006, Bates stamped ETH.MESH.00461576, 15 was marked for identification.) 16 - - - 17 BY MR. SLATER: 18 Q. Let's spend a couple of minutes on 19 this document. 20 Okay. You have before you Exhibit 21 T-1054? 22 A. Yes. 23 Q. This is an internal memorandum or 24 letter written by Price St. Hilaire, Product 25 Director Pelvic Floor Repair, dated October 23,</p>	<p>1 director for the Prolift felt a need to send this 2 letter to the entire Ethicon Women's Health & 3 Urology field sales force to reaffirm the criteria 4 for any person who was invited to be trained on the 5 Prolift, any doctor. Right? 6 A. Yes. 7 Q. And obviously this memo or letter was 8 written because there was obviously an issue at that 9 point with doctors being brought to the training who 10 didn't meet this criteria, so the field sales force 11 was being told, this is our criteria, make sure you 12 meet this criteria. Correct? 13 MR. BROWN: Objection. 14 THE WITNESS: I can't agree to that. 15 BY MR. SLATER: 16 Q. Well, then why would he write the 17 e-mail? Let me rephrase it. 18 Why did Price St. Hilaire send this 19 letter, do you know? 20 A. I don't know as I sit here -- well, 21 let me rephrase it, let me correct my answer. 22 My understanding is that he was 23 reiterating the same criteria that was in effect 24 from the time the Prolift product was launched 25 through present day. This was always the criteria</p>
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<p>1 2006. 2 A. Yes. 3 Q. Price St. Hilaire is a product 4 director in the pelvic floor repair area of 5 marketing? 6 A. Yes. 7 Q. So he's a marketing person. Right? 8 A. Yes. 9 Q. As a product director, he's somebody 10 responsible to market the, in this case we're 11 talking about the Prolift. Correct? 12 A. I can't agree with that. The product 13 director would have multiple responsibilities. 14 Q. Well, he works in marketing. Right? 15 A. He does work in marketing. Correct. 16 Q. So his overall responsibility is to 17 market in this case the Prolift. Right? 18 A. His overall responsibility was to be 19 responsible for the pelvic floor repair products. 20 Q. Now, does marketing within your 21 company -- well, I'll withdraw that. Okay. 22 Let's look at the date of the letter 23 first is October 23, 2006. Right? 24 A. Yes. 25 Q. So as of that point, the product</p>	<p>1 that was involved in the Prolift procedure, and he 2 was recommunicating it out to the sales -- to the 3 field sales organization. 4 Q. The criteria set forth in this letter 5 was the criteria from day one, if a doctor didn't 6 meet this criteria, meaning all six of those 7 criteria, the doctor was precluded by that criteria 8 from being invited to be trained on the Prolift. 9 Correct? 10 A. Yes, that was our intent. 11 Q. If your company -- and -- rephrase. 12 Withdrawn. 13 And your company had set up a system 14 to make sure that if a sales representative invited 15 a doctor to be trained, that the doctor's 16 credentials and background would be double-checked 17 by the division manager and the professional 18 education development manager potentially also, to 19 make sure that the doctor met this criteria, a 20 system of checks and balances. Correct? 21 A. That's correct. 22 Q. If a doctor who did not meet this 23 criteria was trained on the Prolift, then the system 24 of checks and balances within your company failed 25 with regard to that doctor. Correct?</p>

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<p>1 A. I have no knowledge of a doctor not 2 meeting this criteria. 3 Q. I didn't ask you if it happened, so 4 let's ask the question again. 5 If a doctor was brought to the 6 Prolift training and allowed to be trained but he or 7 she did not meet all six of these items of criteria, 8 then the system within your company failed in that 9 instance. If it happened, that would be a failure 10 of the system. Correct? 11 MR. BROWN: Objection. 12 THE WITNESS: I can't agree to that. 13 BY MR. SLATER: 14 Q. Oh, really? 15 So you have a system in place that's 16 supposed to be a system of checks and balances to 17 make sure that a doctor who doesn't meet all six of 18 these criteria will be trained. Right? That's the 19 system. Right? 20 A. That's the intent of the system. 21 Correct. 22 Q. And if a doctor were to be trained 23 who didn't meet this criteria, that would mean that 24 in that instance the system did not work, because a 25 doctor who shouldn't have been trained got trained</p>	<p>1 MR. SLATER: No. Here's what you'll 2 do. You'll say yes, no or I can't answer with a yes 3 or no. 4 THE WITNESS: I can't answer with a 5 yes or no. 6 BY MR. SLATER: 7 Q. Let me ask it again so we can get 8 that clean so I can play it to the jury. Okay? And 9 then they'll see your face up on a 30-foot screen 10 saying you can't answer that simple question with a 11 yes or no. 12 MR. BROWN: Objection to that. 13 Go ahead. 14 BY MR. SLATER: 15 Q. You're telling this jury -- well, 16 rephrase. 17 Answer this question for the jury. 18 If a doctor who did not meet this 19 criteria, all six items, still got through and got 20 trained on the Prolift, if that happened, that would 21 be contrary to the intention of your company because 22 the criteria was set up to prevent that doctor from 23 getting trained on the Prolift. That's a true 24 statement. Right? 25 MR. BROWN: Objection.</p>
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<p>1 on the Prolift. That's a true statement by 2 definition. Correct? 3 A. I can't agree to that. 4 Q. Fine. 5 If a doctor who didn't meet this 6 criteria was trained on the Prolift, that is 7 contrary to what your company wanted to happen. 8 Correct? 9 A. The training on the Prolift -- 10 Q. It's a simple yes-or-no question. 11 Today we're going to actually stick to my questions. 12 You guys are going -- you're not going to do this. 13 So I'm going to ask the question again. 14 If a doctor who did not meet this 15 criteria got trained on the Prolift, that would be 16 contrary to what your company wanted to happen. 17 Correct? 18 MR. BROWN: Objection. 19 Answer it the way that you feel -- 20 MR. SLATER: No. He can answer -- 21 no, no. Hang on. Mr. Brown -- 22 MR. BROWN: If you can answer with a 23 yes, answer with a yes. If you can answer with a 24 no, answer with a no. If you need to qualify yes or 25 no, you can do that.</p>	<p>1 THE WITNESS: I can't answer that 2 with a yes or no. 3 BY MR. SLATER: 4 Q. Fine. 5 A. Because -- 6 Q. I didn't ask you for a because. I 7 asked you yes, no or you can't answer with a yes or 8 no. You've told the jury you can't answer that 9 question with a yes or no, so that's fine. Okay? 10 Let's go to the next question. 11 Your doctor -- rephrase. 12 Ethicon set up this criteria, these 13 six items of criteria, with the intention that only 14 doctors who meet all of that criteria would be 15 trained on the Prolift because your company had made 16 a decision, a carefully thought-out decision, that 17 those are the doctors who would be able to safely 18 and effectively treat patients with the Prolift. 19 Right? 20 A. I can't answer that question. 21 Q. This criteria was set up for a 22 reason. Right? 23 A. I believe so, yes. 24 Q. The reason was to make sure that 25 doctors of only a certain level of skill and</p>

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<p>1 experience would be allowed to be trained on the</p> <p>2 Prolift. Right?</p> <p>3 A. The intent of this criteria was to</p> <p>4 provide criteria to the sales force who was</p> <p>5 recruiting for these programs to invite doctors to</p> <p>6 the training. This training was not the only</p> <p>7 training that was made available to the doctors.</p> <p>8 The doctors had experience in ob/gyn, urogynecology</p> <p>9 or urology. They were board certified. Many of</p> <p>10 them had fellowship training in addition in this</p> <p>11 particular area. The company made every effort to</p> <p>12 make sure the best doctors were trained to do this</p> <p>13 procedure in order to provide the best possible</p> <p>14 outcomes for patients.</p> <p>15 MR. SLATER: Move to strike.</p> <p>16 BY MR. SLATER:</p> <p>17 Q. The system -- rephrase.</p> <p>18 The system of checks and balances was</p> <p>19 set up so that doctors who don't meet this criteria</p> <p>20 wouldn't slip through and get trained. That's why</p> <p>21 you have several different people looking at the</p> <p>22 doctor's credentials and background before he's</p> <p>23 allowed or she's allowed to be trained. Right?</p> <p>24 That's why you have checks and balances. Right?</p> <p>25 A. Yes.</p>	<p>1 need to meet this criteria when you bring doctors</p> <p>2 in. Correct?</p> <p>3 A. That's consistent with my</p> <p>4 recollection as I sit here today.</p> <p>5 Q. And I showed you e-mails yesterday in</p> <p>6 2007 showing that doctors were still complaining to</p> <p>7 Ethicon, preceptors were complaining to Ethicon,</p> <p>8 that the quality of the doctors coming to the</p> <p>9 training was falling below the level of skill that</p> <p>10 they -- that was supposed to be met. Remember we</p> <p>11 showed you that e-mail yesterday?</p> <p>12 MR. BROWN: Objection.</p> <p>13 THE WITNESS: I remember one e-mail</p> <p>14 that you showed me from yesterday.</p> <p>15 BY MR. SLATER:</p> <p>16 Q. And do you recall -- well, rephrase.</p> <p>17 Withdrawn.</p> <p>18 This was Exhibit 1052, March 29,</p> <p>19 2007. So it's about five months, six months after</p> <p>20 Price St. Hilaire's letter where Andrew Meek is</p> <p>21 reporting to several people, including yourself,</p> <p>22 that Dr. Sarmini raised a concern that he is seeing</p> <p>23 much lower skill levels from the preceptees at his</p> <p>24 Prolift courses this year.</p> <p>25 So the problem was continuing even</p>
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<p>1 Q. If a doctor who didn't meet this</p> <p>2 criteria got through and got trained anyway, that</p> <p>3 would be a failure of the system of checks and</p> <p>4 balances. Correct?</p> <p>5 A. I have no knowledge of a doctor not</p> <p>6 meeting this criteria being trained.</p> <p>7 Q. If it happened, that would be a</p> <p>8 failure of the system of checks and balances.</p> <p>9 Correct?</p> <p>10 A. I can't answer that with a yes or no.</p> <p>11 Q. One of the reasons why doctors would</p> <p>12 need to meet this criteria from the perspective of</p> <p>13 Ethicon professional education was because it was</p> <p>14 determined within your company that those would be</p> <p>15 the doctors who would have the best chance to safely</p> <p>16 and effectively use the Prolift. Correct?</p> <p>17 A. I would defer that question to</p> <p>18 medical affairs.</p> <p>19 Q. At the point when this letter was</p> <p>20 written by Price St. Hilaire to the sales force,</p> <p>21 there was some concern being voiced by preceptors</p> <p>22 back to your company that they were seeing</p> <p>23 physicians being brought to the training who didn't</p> <p>24 meet this criteria. That's why this refresher</p> <p>25 letter was sent to the sales force to say you really</p>	<p>1 five or six months later. Correct?</p> <p>2 A. I can't answer that with a yes or a</p> <p>3 no. Dr. Sarmini is raising a concern. We did</p> <p>4 address Dr. Sarmini's concern and we added</p> <p>5 additional materials into the Prolift training, as</p> <p>6 well as a hands-on training model and an electronic</p> <p>7 simulator that were used. I don't agree as I sit</p> <p>8 here today with the observation that Dr. Sarmini may</p> <p>9 have been making in this e-mail from 2007. However,</p> <p>10 we did take his input and, as always, tried to do</p> <p>11 our best to make our education as robust as</p> <p>12 possible.</p> <p>13 MR. SLATER: Move to strike after "I</p> <p>14 can't answer with a yes or no."</p> <p>15 BY MR. SLATER:</p> <p>16 Q. Ethicon felt that it was its duty to</p> <p>17 strictly enforce the criteria set forth in Price St.</p> <p>18 Hilaire's letter from the first day the Prolift was</p> <p>19 launched and the training began. Correct?</p> <p>20 A. This was one of the criteria that was</p> <p>21 provided for the Prolift product from the time it</p> <p>22 was launched, yes.</p> <p>23 Q. And Ethicon felt that it was its duty</p> <p>24 to strictly enforce that criteria and that's why the</p> <p>25 system of checks and balances was put into effect so</p>

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<p style="text-align: right;">Page 318</p> <p>1 that doctors who don't meet this criteria wouldn't</p> <p>2 slip through. Correct?</p> <p>3 MR. BROWN: Objection.</p> <p>4 THE WITNESS: That's not correct.</p> <p>5 BY MR. SLATER:</p> <p>6 Q. Fine.</p> <p>7 A. The system of checks and balances --</p> <p>8 Q. Well, you said just said it's not</p> <p>9 correct.</p> <p>10 A. -- applies to all of our products --</p> <p>11 Q. Sir --</p> <p>12 A. -- and all of our training that we've</p> <p>13 been doing since we started professional education</p> <p>14 over 20 years ago.</p> <p>15 Q. Okay.</p> <p>16 The system of checks and balances to</p> <p>17 make sure that only those doctors who meet the</p> <p>18 proper criteria per your company, there's always</p> <p>19 been a system of checks and balances for all the</p> <p>20 devices on which your company has trained</p> <p>21 physicians. Correct?</p> <p>22 MR. BROWN: Objection.</p> <p>23 THE WITNESS: To my knowledge, within</p> <p>24 Ethicon, yes.</p> <p>25 BY MR. SLATER:</p>	<p style="text-align: right;">Page 320</p> <p>1 trained on any of the pelvic mesh devices sold by</p> <p>2 Ethicon and that doctor didn't meet the training</p> <p>3 criteria for that device's training, in that</p> <p>4 instance, the system of checks and balances would</p> <p>5 have not worked because the doctor got through and</p> <p>6 was trained despite the fact that he or she was not</p> <p>7 supposed to be.</p> <p>8 That's a true statement, isn't it?</p> <p>9 MR. BROWN: Objection.</p> <p>10 THE WITNESS: I can't agree to that.</p> <p>11 BY MR. SLATER:</p> <p>12 Q. So you think in that instance if the</p> <p>13 doctor got through and got trained, that the system</p> <p>14 of checks and balances -- that the system of checks</p> <p>15 and balances worked?</p> <p>16 A. I can't answer that with a yes or no</p> <p>17 because --</p> <p>18 Q. Fine. That's all -- no. There's no</p> <p>19 because. We don't have a because. That's what your</p> <p>20 attorney can ask you later if he wants to continue</p> <p>21 on this line of questioning. Okay, sir?</p> <p>22 Counsel asked you about the types of</p> <p>23 materials that are provided to physicians in</p> <p>24 professional education, and one of the things that</p> <p>25 you said is clinical articles are provided to</p>
<p style="text-align: right;">Page 319</p> <p>1 Q. So across the board, every pelvic</p> <p>2 mesh device Ethicon has sold, if a doctor was</p> <p>3 trained and that doctor did not meet the criteria</p> <p>4 that had been set by the company for doctors to be</p> <p>5 brought to the training, in every one of those</p> <p>6 instances, that would be a failure of the system of</p> <p>7 checks and balances because that doctor was not</p> <p>8 supposed to get through and get trained.</p> <p>9 That's a true statement, yes or no?</p> <p>10 A. No.</p> <p>11 Q. So if the system of checks and</p> <p>12 balances didn't cap -- didn't catch a doctor who</p> <p>13 didn't meet the criteria, you think the</p> <p>14 checks-and-balances system worked?</p> <p>15 A. There were other factors that went</p> <p>16 into this. At the end of the day, I feel like we</p> <p>17 did everything we could to provide criteria and then</p> <p>18 provided a robust system of checks and balances to</p> <p>19 make sure it happened.</p> <p>20 Q. I didn't ask you that, though.</p> <p>21 Strike your answer. You keep telling me that you</p> <p>22 think you guys did a wonderful job. I'm not asking</p> <p>23 you that. I'm saying, in any instance --</p> <p>24 Here's the question.</p> <p>25 In any instance where a doctor was</p>	<p style="text-align: right;">Page 321</p> <p>1 doctors through professional education. That's one</p> <p>2 of the types of materials provided. You said that.</p> <p>3 Right?</p> <p>4 A. Yes.</p> <p>5 Q. Would those clinical articles</p> <p>6 actually be handed to doctors at professional</p> <p>7 education training sessions?</p> <p>8 A. Yes.</p> <p>9 Q. And your company certainly had an</p> <p>10 obligation when deciding what articles to give, to</p> <p>11 make sure that the decisions on what articles to</p> <p>12 give would be fair and balanced, meaning you</p> <p>13 wouldn't only want to give the articles that were</p> <p>14 favorable to the device that the doctors were being</p> <p>15 trained on but also articles that were critical of</p> <p>16 it or may have raised serious concerns about the</p> <p>17 safety or effectiveness of the device. You want to</p> <p>18 give both sides. Right?</p> <p>19 A. Yes.</p> <p>20 Q. If your company failed to do that,</p> <p>21 your company did not act in a fair and balanced way.</p> <p>22 Correct?</p> <p>23 A. I can't answer that with a yes or no.</p> <p>24 Q. Fine.</p> <p>25 You'd have to ask medical affairs on</p>

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<p>1 that one?</p> <p>2 A. Is that a question?</p> <p>3 Q. Yeah.</p> <p>4 Do you think you'd have to defer to</p> <p>5 medical affairs on that one?</p> <p>6 A. As I sit here today, if you could</p> <p>7 repeat the question, I'm not sure I understood the</p> <p>8 second question.</p> <p>9 Q. Sure.</p> <p>10 If your company in giving medical</p> <p>11 literature to doctors at professional education</p> <p>12 events failed to give articles on both sides of the</p> <p>13 issue, those that are favorable and those that were</p> <p>14 not favorable, then your company failed to provide</p> <p>15 fair and balanced medical literature to doctors.</p> <p>16 Correct?</p> <p>17 A. My understanding is that we did</p> <p>18 provide fair and balanced --</p> <p>19 MR. SLATER: Move to strike.</p> <p>20 THE WITNESS: -- medical literature</p> <p>21 on those products.</p> <p>22 BY MR. SLATER:</p> <p>23 Q. I didn't ask you what you did. I</p> <p>24 didn't ask you what you actually did. You keep</p> <p>25 saying that. We have a difference of opinion,</p>	<p>1 literature, I would defer that question to medical</p> <p>2 affairs.</p> <p>3 Q. Did your company in professional</p> <p>4 education provide the Cheryl Iglesia article</p> <p>5 published in August of 2010 to doctors through</p> <p>6 professional education?</p> <p>7 A. We may have.</p> <p>8 Q. The one that said that it didn't</p> <p>9 appear that the Prolift mesh was any more</p> <p>10 efficacious than native tissue repair but showed</p> <p>11 that it had much more complications and more serious</p> <p>12 complications?</p> <p>13 MR. BROWN: Objection.</p> <p>14 THE WITNESS: We may have, I can't</p> <p>15 recall as I sit --</p> <p>16 BY MR. SLATER:</p> <p>17 Q. I'm going to withdraw the question</p> <p>18 and rephrase it.</p> <p>19 Did professional education for</p> <p>20 Ethicon hand out the Iglesia, et al. article</p> <p>21 published in 2010 as part of professional education?</p> <p>22 A. It's possible. I can't recall as I</p> <p>23 sit here today.</p> <p>24 Q. If your company acted in a fair and</p> <p>25 balanced way, then that article should have been</p>
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<p>1 because I don't think you did. But I'm not asking</p> <p>2 you that question.</p> <p>3 A. Okay. I thought it mattered what</p> <p>4 actually happened.</p> <p>5 Q. Oh, it does matter.</p> <p>6 MR. BROWN: No, no, no. Wait.</p> <p>7 MR. SLATER: We'll get to that.</p> <p>8 MR. BROWN: Just listen. He's asking</p> <p>9 you a question --</p> <p>10 THE WITNESS: Sure. I'm sorry.</p> <p>11 MR. BROWN: -- with regard to it</p> <p>12 being -- listen to his question, answer his question</p> <p>13 with regard to would that be fair and balanced or</p> <p>14 not.</p> <p>15 THE WITNESS: Okay.</p> <p>16 BY MR. SLATER:</p> <p>17 Q. If your company failed to give</p> <p>18 medical literature to doctors on both sides of the</p> <p>19 issue, meaning literature that would be favorable to</p> <p>20 the device being trained on and that unfavorable,</p> <p>21 for example, articles questioning the safety and</p> <p>22 effectiveness of the device, if your company didn't</p> <p>23 provide both sides, then it failed to provide fair</p> <p>24 and balanced medical literature. Correct?</p> <p>25 A. Since we're talking about medical</p>	<p>1 provided to doctors. Right?</p> <p>2 MR. BROWN: Objection.</p> <p>3 THE WITNESS: I can't answer that</p> <p>4 question.</p> <p>5 BY MR. SLATER:</p> <p>6 Q. You can't as the director of</p> <p>7 professional education and the corporate</p> <p>8 representative, you can't answer that?</p> <p>9 A. I can't answer that question.</p> <p>10 Q. You know the Cheryl Iglesia article.</p> <p>11 Right?</p> <p>12 A. As I sit here today, I can't recall</p> <p>13 the specific article that you're referring to.</p> <p>14 Q. That's what you're telling this jury</p> <p>15 under oath, that you're not familiar with the</p> <p>16 article that was authored by the lead author, Cheryl</p> <p>17 Iglesia, in August of 2010 published?</p> <p>18 A. I may have seen it over the years. I</p> <p>19 can't recall that specific article or what its</p> <p>20 conclusions were or what its basis was as I sit here</p> <p>21 today.</p> <p>22 Q. You testified that something else</p> <p>23 that would be -- rephrase.</p> <p>24 You testified that one form of</p> <p>25 professional education that was used for devices</p>

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<p>1 including the Prolift was webcasts. Remember you</p> <p>2 said that?</p> <p>3 A. Yes.</p> <p>4 Q. List for me all the webcasts with</p> <p>5 regard to the Prolift that ever existed, all the</p> <p>6 ones that occurred.</p> <p>7 A. I can't list that as I sit here</p> <p>8 today.</p> <p>9 Q. Why not?</p> <p>10 A. Because there were numerous ones.</p> <p>11 Q. How many?</p> <p>12 A. I can't tell you as I sit here today.</p> <p>13 Q. Give me an estimate. Give me a</p> <p>14 range. Were there two? Were there 35? Give me a</p> <p>15 range.</p> <p>16 A. Probably somewhere in between there.</p> <p>17 Q. Closer to what? Give me the best</p> <p>18 estimate you can give me.</p> <p>19 A. The best estimate that I could give</p> <p>20 would probably be somewhere around 15.</p> <p>21 Q. Were they all videotaped? Meaning</p> <p>22 was the video feed recorded and saved for every</p> <p>23 single one of those webcasts?</p> <p>24 A. I'm not certain. I believe so, but I</p> <p>25 can't say that with certainty as I sit here today.</p>	<p>1 Q. How about one?</p> <p>2 A. -- personal knowledge of webcasts</p> <p>3 being used for the TVT products, telesurgeries,</p> <p>4 which is a type of webcast, were also used for the</p> <p>5 TVT, Prolift and Prosima products.</p> <p>6 Q. Just for the record, what is a</p> <p>7 "webcast" as you're using the term?</p> <p>8 A. A webcast would be a video</p> <p>9 transmission over the Internet of a presentation</p> <p>10 with a surgeon speaking. Oftentimes, it would</p> <p>11 include surgical video or -- yeah, or surgery of</p> <p>12 other video content.</p> <p>13 Q. What is telesurgery?</p> <p>14 A. Telesurgery can also be transmitted</p> <p>15 over the web. The only difference between the two</p> <p>16 is that telesurgery requires special satellite</p> <p>17 equipment versus transmitting the same type of</p> <p>18 information over the Internet.</p> <p>19 Q. You also listed online training.</p> <p>20 Is that something different from</p> <p>21 webcasts and telesurgery or is it the same category?</p> <p>22 A. Online would be included in that same</p> <p>23 category.</p> <p>24 Q. Tell me every single Prolift webcast</p> <p>25 that you can remember right now.</p>
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<p>1 Q. Was a transcript of each webcast</p> <p>2 created and maintained?</p> <p>3 A. I'm not certain.</p> <p>4 Q. You're the corporate rep. We're here</p> <p>5 for your deposition. Counsel elicited this from</p> <p>6 you.</p> <p>7 Are you telling me you're not</p> <p>8 prepared to answer these questions about</p> <p>9 approximately 15 or potentially more webcasts that</p> <p>10 were used for professional education on the Prolift?</p> <p>11 MR. BROWN: Objection.</p> <p>12 THE WITNESS: I can't recall as I sit</p> <p>13 here today.</p> <p>14 BY MR. SLATER:</p> <p>15 Q. And were webcasts used for the other</p> <p>16 devices sold by your company?</p> <p>17 MR. BROWN: Objection.</p> <p>18 THE WITNESS: Sometimes, yes.</p> <p>19 BY MR. SLATER:</p> <p>20 Q. Can you tell me all of the ones for</p> <p>21 all of the other devices, all the TVT devices, the</p> <p>22 Prosima, the Prolift+M, every one of those, can you</p> <p>23 give me all the webcasts for those?</p> <p>24 A. I can't give them all to you as I sit</p> <p>25 here today. However, I have --</p>	<p>1 MR. BROWN: Objection.</p> <p>2 MR. SLATER: What are you objecting</p> <p>3 to? You opened the door on this.</p> <p>4 MR. BROWN: What are you asking him?</p> <p>5 Are you asking him for every bit of the content from</p> <p>6 what was said? Are you asking him --</p> <p>7 MR. SLATER: I got your objection.</p> <p>8 BY MR. SLATER:</p> <p>9 Q. Let's start general.</p> <p>10 Tell me as best you can each webcast</p> <p>11 event, just tell me each time there was a webcast</p> <p>12 for the Prolift that you actually can recall. Give</p> <p>13 me whatever information you know about each one.</p> <p>14 Let's start with the first one you</p> <p>15 can recall.</p> <p>16 MR. BROWN: Objection.</p> <p>17 THE WITNESS: It's hard to remember.</p> <p>18 BY MR. SLATER:</p> <p>19 Q. I didn't ask you if it's hard to</p> <p>20 remember. So let's start over.</p> <p>21 Just tell me the list. Okay? So</p> <p>22 I'll ask the question now.</p> <p>23 Please list for me each webcast that</p> <p>24 you recall with regard to the Prolift. Just give me</p> <p>25 whatever information you can remember about each</p>

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<p>1 one. So start with one, you can tell me what you 2 know about that one, then you can tell me what you 3 recall about another one. As many as you can 4 recall. Let's start with this. 5 Tell me the first one, anything you 6 know about it. 7 A. The first ones I can recall were in 8 the early 2005 and 2006 period where surgeries were 9 transmitted through the webcast or through the 10 telesurgery. 11 Q. Who was involved in those surgeries? 12 A. Likely -- and I can't remember as I 13 sit here today specifically. It would be likely one 14 of our surgeon preceptors who were teaching Prolift. 15 Q. What are their names? 16 A. Dr. Lucente, Dr. Miller, 17 Dr. Robinson. Those are some of the names that I 18 can recall that may have been involved in those. 19 Q. And that would have been actual 20 Prolift procedures being shown on the Internet? 21 A. To surgeons, yes. 22 Q. What was the criteria for a doctor to 23 be allowed to participate in watching a webcast or a 24 telesurgery? 25 A. The same -- similar criteria to what</p>	<p>1 have to look at the -- some of the references that 2 we had to see if there was a date. 3 Is this everything that I had 4 yesterday? 5 This is from the three year time 6 period that I wasn't directly involved in the 7 business, but it's my understanding that this may 8 have been presented as a webcast or in other venues. 9 Q. Just identify for the record what 10 you're holding in your hand. 11 A. T-1045. 12 Q. That's the Prolift+M Advanced User 13 Discussion? 14 A. I believe so. 15 Q. Who presented that? 16 A. I wasn't with the company at the 17 time, so I don't know. 18 Q. Sir, you keep saying you weren't with 19 the company. You are designated by the company as 20 the corporate rep. So please understand that under 21 the court -- the rules of law in New Jersey, that's 22 an irrelevant statement. 23 MR. BROWN: Do you know or not know? 24 THE WITNESS: I don't know. I'm 25 sure -- I don't know.</p>
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<p>1 was listed here. 2 Q. So in order to be able to participate 3 and watch this, you'd have to meet the six criteria 4 on that letter. Correct? 5 A. Well, this letter is specific to 6 attending live training, face-to-face training. 7 Q. It doesn't say that, though, does it? 8 Trained, integrity of the quality of physicians 9 trained for the Prolift. It doesn't say anything 10 about live versus the webcast, and the webcasts 11 constitute training. Right? Correct? 12 A. The webcasts are a type of training. 13 I believe that this document specifically refers to 14 training in a lab setting, a preceptorship type of 15 setting. 16 Q. But the same criteria would apply to 17 allow a doctor to participate in watching a webcast 18 or online training or telesurgery. Correct? 19 A. The intent would be that, yes. 20 Q. So you told me there was some surgery 21 webcasts in early 2005 into 2006 involving likely 22 Dr. Lucente, Dr. Miller and Dr. Robinson. 23 What else? Tell me other Prolift 24 webcasts you can recall. 25 A. I believe there was a webcast, and I</p>	<p>1 BY MR. SLATER: 2 Q. So we can bring you back at some 3 future date to get all the details on all the 4 webcasts and who was involved in teaching that 5 advanced user discussion. You could get that 6 information and be prepared to testify about it on a 7 future day. Correct? 8 MR. BROWN: Objection. 9 THE WITNESS: Certainly I'd be 10 willing to try to get that information. 11 BY MR. SLATER: 12 Q. Any other webcasts regarding the 13 Prolift that you can tell me about? And just for 14 the record, by the way, T-1045 is Prolift+M? 15 A. Yes. I agree with that. 16 Q. But you are lumping Prolift and 17 Prolift+M together, basically? 18 A. I'm not lumping them together. Now 19 that you've corrected me, I notice that that's 20 Prolift+M. 21 Q. Any other Prolift webcasts, online 22 training, telesurgery, anything you can tell me you 23 recall as you sit here now? 24 A. There may have been other 25 telesurgeries performed by other surgeons.</p>

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<p>1 Q. I just want to know what you can</p> <p>2 recall.</p> <p>3 A. I'm trying to recall the best that I</p> <p>4 can, as I sit here today, that the ones that I have</p> <p>5 described already are the types of ones that I would</p> <p>6 be aware of having happened.</p> <p>7 Q. With regard to the TVT devices, do</p> <p>8 you recall any specific webcasts, online training or</p> <p>9 telesurgeries that ever existed with any of the TVT</p> <p>10 devices?</p> <p>11 A. Yes.</p> <p>12 Q. Tell us the list.</p> <p>13 A. I believe that there were televised</p> <p>14 videos on televised surgery of the TVT-O in around</p> <p>15 2004 and 2005.</p> <p>16 Q. And who was involved in providing</p> <p>17 that teaching? Who was the person who presented, or</p> <p>18 people?</p> <p>19 A. It was probably multiple surgeons</p> <p>20 presenting.</p> <p>21 Q. Who?</p> <p>22 A. And our medical affairs department.</p> <p>23 At the time, Dr. Lucente may have been involved.</p> <p>24 Dr. de Leval, who was the inventor, may have been</p> <p>25 involved. There may have been others as well that I</p>	<p>1 Q. It would have to convey, for example,</p> <p>2 the known adverse events and risks as well.</p> <p>3 Correct?</p> <p>4 A. Yes.</p> <p>5 Q. And the last device I want to ask you</p> <p>6 about is the Prosima.</p> <p>7 First of all, what you just said</p> <p>8 would also apply to the Prosima. I didn't have it</p> <p>9 in the list, though. Right?</p> <p>10 A. I'm sorry, can you --</p> <p>11 Q. The list of things that you just told</p> <p>12 me about what the webcasts and online training would</p> <p>13 have to convey, that would apply to the Prosima as</p> <p>14 well. Correct?</p> <p>15 A. Yes.</p> <p>16 Q. Was there any webcasts or online</p> <p>17 training with regard to the Prosima that you can</p> <p>18 recall?</p> <p>19 A. As I sit here today, I can't recall,</p> <p>20 but there may have been.</p> <p>21 Q. The surgeons -- well, rephrase.</p> <p>22 The doctors who provide the training</p> <p>23 for Ethicon, meaning the outside doctors, they get</p> <p>24 paid to do that. Right?</p> <p>25 A. Yes.</p>
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<p>1 can't recall from that -- from 2005.</p> <p>2 Q. Any other webcasts, online training,</p> <p>3 telesurgery, with regard to any TVT devices that you</p> <p>4 can recall other than what you just told me?</p> <p>5 A. I believe there were some webcasts on</p> <p>6 TVT SECUR as well with -- transmitting video of</p> <p>7 surgery as well.</p> <p>8 Q. Who was involved in that?</p> <p>9 A. Those I can't recall. It would have</p> <p>10 been one of our surgeon faculty or preceptors that</p> <p>11 teach on behalf of TVT SECUR.</p> <p>12 Q. Any other that you recall?</p> <p>13 A. As I sit here today, I can't recall</p> <p>14 if there were others.</p> <p>15 Q. Any of these webcasts, online</p> <p>16 training or telesurgeries for any of the pelvic mesh</p> <p>17 devices would need to be accurate and convey</p> <p>18 accurate information. Correct?</p> <p>19 A. Yes.</p> <p>20 Q. It would have to convey fair and</p> <p>21 balanced information. Correct?</p> <p>22 A. Yes.</p> <p>23 Q. It would have to convey the material</p> <p>24 risk information. Correct?</p> <p>25 A. Yes.</p>	<p>1 Q. You said that if a doctor who had</p> <p>2 been trained experienced problems or complications</p> <p>3 with their patients, one aspect of professional</p> <p>4 education is they could call the doctor that trained</p> <p>5 him or her and get information about how to treat</p> <p>6 those complications. Right?</p> <p>7 A. They could ask questions of the</p> <p>8 doctor that trained them, sure.</p> <p>9 Q. And your company would facilitate</p> <p>10 that if asked. Correct?</p> <p>11 A. Yes.</p> <p>12 Q. And that would happen fairly often.</p> <p>13 Right?</p> <p>14 A. I can't say with what frequency it</p> <p>15 happened.</p> <p>16 Q. Your company -- well, rephrase.</p> <p>17 Withdrawn.</p> <p>18 You said that you did not establish</p> <p>19 the professional education content, the actual</p> <p>20 content of the training materials. Right?</p> <p>21 A. That's correct.</p> <p>22 Q. Certainly, it was not only created by</p> <p>23 surgeons and doctors who didn't work for the company</p> <p>24 or in medical affairs, other people participated</p> <p>25 from other departments in the company. Right?</p>

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<p>1 A. I believe there were cross-functional</p> <p>2 people from different areas of the company.</p> <p>3 Q. The marketing department</p> <p>4 participated. Correct?</p> <p>5 A. Yes.</p> <p>6 Q. The professional education department</p> <p>7 participated. Correct?</p> <p>8 A. Yes.</p> <p>9 Q. Would regulatory have participated?</p> <p>10 A. They would have been on the copy</p> <p>11 review board.</p> <p>12 Q. Who else? What other department?</p> <p>13 A. Medical affairs, our surgeon</p> <p>14 preceptors, regulatory, quality. I'm trying to</p> <p>15 think of all the different cross-functional members.</p> <p>16 The legal department. Those are the ones I can</p> <p>17 recall as I sit here today.</p> <p>18 Q. You were asked some questions about</p> <p>19 the language within the professional education</p> <p>20 materials. It certainly was important for you, as</p> <p>21 director of professional education, and other people</p> <p>22 within your department, to understand what the</p> <p>23 content -- what the words stated on the page meant.</p> <p>24 You needed to know what you were telling doctors.</p> <p>25 Right?</p>	<p>1 what information would be provided in those webcasts</p> <p>2 and online training. Correct?</p> <p>3 A. Yes.</p> <p>4 Q. Was the content preapproved through</p> <p>5 your company to make sure that your company approved</p> <p>6 of what was going to be conveyed?</p> <p>7 A. Yes.</p> <p>8 Q. Would that be a copy review process?</p> <p>9 A. Yes.</p> <p>10 Q. Let's go to Exhibit 127, the first</p> <p>11 Prolift professional education deck. Go to the part</p> <p>12 about the TVM retrospective study, the page that has</p> <p>13 the postoperative complications that we've</p> <p>14 discussed.</p> <p>15 A. Can I see the page that you're</p> <p>16 referring to?</p> <p>17 Q. It's the one that says, "Vaginal</p> <p>18 exposure with mesh: 25"?</p> <p>19 A. Great. Thank you.</p> <p>20 Q. Are you with me?</p> <p>21 A. I am, yes, thanks.</p> <p>22 Q. In this professional education deck,</p> <p>23 Exhibit 127, there's the page with the postoperative</p> <p>24 complications listed from the TVM retrospective</p> <p>25 study. Do you see that? You have that page in</p>
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<p>1 A. I wasn't making the presentations,</p> <p>2 nor were the people in my department.</p> <p>3 Q. Did your department -- the people --</p> <p>4 rephrase.</p> <p>5 Did the people working in your</p> <p>6 department think it was important to understand what</p> <p>7 was being conveyed in these professional education</p> <p>8 materials?</p> <p>9 A. To the best of our ability as</p> <p>10 nonmedical doctors, we made every attempt to</p> <p>11 understand what information was in these slide</p> <p>12 decks. However, we were not the ones that were</p> <p>13 presenting the materials. It was surgeons</p> <p>14 presenting to other surgeons.</p> <p>15 Q. With regard to all of the</p> <p>16 professional education materials we've discussed,</p> <p>17 they would all have to be copy reviewed. Right?</p> <p>18 A. Yes.</p> <p>19 Q. And they would be signed off on by</p> <p>20 multiple departments, including professional</p> <p>21 education, marketing, medical affairs, regulatory,</p> <p>22 quality. Correct?</p> <p>23 A. Yes.</p> <p>24 Q. With regard to the webcasts, the</p> <p>25 content of the webcasts, your company had input into</p>	<p>1 front of you. Right?</p> <p>2 A. Yes.</p> <p>3 Q. On this page it says that the number</p> <p>4 of patients who had vaginal exposure was 25 of the</p> <p>5 patients. Right?</p> <p>6 A. The number of patients that required</p> <p>7 surgical partial resection of the mesh was 25 and</p> <p>8 had vaginal exposure was 25 patients.</p> <p>9 Q. Let me start over.</p> <p>10 The word on the page says, "Vaginal</p> <p>11 exposure with mesh: 25" patients "(9.2%)."</p> <p>12 That's what that line says. Right?</p> <p>13 A. That's what that line says. Correct.</p> <p>14 Q. The next line, there's a bullet point</p> <p>15 that says, "Required surgical partial resection."</p> <p>16 Right?</p> <p>17 A. Yes. That's a subbullet of the</p> <p>18 previous -- of the previous bullet. Those two go</p> <p>19 together.</p> <p>20 Q. Then on the next page, it says,</p> <p>21 "Uterine Conservation Decreases Exposure Rate." Do</p> <p>22 you see that?</p> <p>23 A. I do, yes.</p> <p>24 Q. And it says that the patients who had</p> <p>25 hysterectomies had 24 exposures and the patients who</p>

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<p>1 had no hysterectomy or a previous hysterectomy had</p> <p>2 one exposure. Do you see that?</p> <p>3 A. Yes.</p> <p>4 Q. That's telling the doctors there that</p> <p>5 there is a total of 25 exposures. That's what it</p> <p>6 says on that page. Right?</p> <p>7 A. It's referring to the previous page</p> <p>8 and those 25 --</p> <p>9 MR. SLATER: Move to strike.</p> <p>10 THE WITNESS: -- exposures that</p> <p>11 require --</p> <p>12 MR. SLATER: Move to strike.</p> <p>13 THE WITNESS: -- partial surgical</p> <p>14 resection.</p> <p>15 BY MR. SLATER:</p> <p>16 Q. Okay.</p> <p>17 Now, stick with my question. I'm not</p> <p>18 off this page yet.</p> <p>19 A. Sure. Sorry.</p> <p>20 Q. On this page, the total number of</p> <p>21 exposures disclosed is 25. Right?</p> <p>22 A. On this page, yes.</p> <p>23 Q. Let's go to the next page, entitled</p> <p>24 "Technique Impacts Exposure Rates." Do you see</p> <p>25 that? Do you see that?</p>	<p>1 disclose that. There aren't any notes on what you</p> <p>2 just said. I want to let you know that. So let's</p> <p>3 just stick with my question.</p> <p>4 On this page --</p> <p>5 MR. BROWN: Move to strike that</p> <p>6 question.</p> <p>7 BY MR. SLATER:</p> <p>8 Q. Rephrase.</p> <p>9 On this page that says, "Defect Type</p> <p>10 Impacts Exposure Rates," for anterior it says 33</p> <p>11 exposures; for posterior, 1 exposure. It's the only</p> <p>12 place in this deck where there's any information</p> <p>13 that one could put together to say, oh, there were</p> <p>14 34 exposures. It's the only page where that number</p> <p>15 can appear. Right?</p> <p>16 A. It's possible, but it was a part of</p> <p>17 the discussion.</p> <p>18 Q. Sir, it's not possible. Sir, it's</p> <p>19 not possible. It's the only place where one could</p> <p>20 add up the exposures to a 34 number. It's not</p> <p>21 anywhere else in this deck. Right?</p> <p>22 A. I'm not certain. I haven't looked</p> <p>23 through the entire deck.</p> <p>24 Q. Well, then look. It's only five</p> <p>25 pages, sir.</p>
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<p>1 A. Yes.</p> <p>2 Q. And that at the bottom of the page is</p> <p>3 21 exposures, 3 exposures and 1, for a total of 25</p> <p>4 exposures disclosed on this page. Correct?</p> <p>5 A. Yes.</p> <p>6 Q. Let's go to the next page, the</p> <p>7 page -- rephrase.</p> <p>8 On the next page, it says, "Defect</p> <p>9 Type Impacts Exposure Rates." And on that page,</p> <p>10 there's anterior and posterior, and it's broken down</p> <p>11 with 33 exposures for one and 1 exposure for the</p> <p>12 other. Right?</p> <p>13 A. Yes.</p> <p>14 Q. So that's telling -- that says a</p> <p>15 total of 34 exposures. Right?</p> <p>16 A. That's correct.</p> <p>17 Q. That's the only place in this entire</p> <p>18 deck where one could add up the exposures in one</p> <p>19 place and see 34 exposures. Right?</p> <p>20 A. It was part of the discussion</p> <p>21 throughout the presentation of the entire deck --</p> <p>22 MR. SLATER: Move to strike.</p> <p>23 BY MR. SLATER:</p> <p>24 Q. Sir, first of all, I just want to let</p> <p>25 you know, we looked at the notes. It doesn't</p>	<p>1 A. Well, actually, the entire deck is --</p> <p>2 Q. The part about the TVM retrospective</p> <p>3 study is only a small part of this. So you can look</p> <p>4 at the few pages and you can confirm for me that</p> <p>5 there's no indication of 34 exposures on any other</p> <p>6 page.</p> <p>7 A. The prior page, if you go one page</p> <p>8 prior to that.</p> <p>9 Q. The page that says "Technique Impacts</p> <p>10 Exposure Rates"?</p> <p>11 A. Right. So I'm looking in</p> <p>12 parentheses. And I can't -- I don't know exactly</p> <p>13 what this means as I sit here today, I defer this to</p> <p>14 medical affairs, but I do see the number 33 erosions</p> <p>15 listed on this page. So I think what they were</p> <p>16 trying to do is break down the different types of</p> <p>17 erosions, what caused the different types of</p> <p>18 erosions and then how a surgeon might be able to</p> <p>19 prevent those different types of erosions.</p> <p>20 Q. But ultimately --</p> <p>21 So you have 25 out of 33 erosions in</p> <p>22 this parentheses at the top. We know there's not 33</p> <p>23 erosions reported in the article. Right? Because</p> <p>24 that number is just wrong, because the article said</p> <p>25 34. Correct?</p>

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<p>1 A. The article, I believe it said 34. 2 Correct. 3 Q. Then at the bottom there's a total of 4 25 exposures called out specifically. Right? 5 A. Which is -- yes. 6 Q. So this is fairly confusing, isn't 7 it? 8 MR. BROWN: Objection. 9 THE WITNESS: No. 10 BY MR. SLATER: 11 Q. Of the 34 exposures seen in that 12 study, 25 required surgical repair. That's 13 73 percent per the article. Correct? 14 A. The article that you showed me did 15 not just refer to Prolift, so that number quoted of 16 73 percent referred to a variety of different meshes 17 and -- 18 Q. Sir, you're on the wrong article. 19 You're getting confused. 20 I showed you the article for the 277 21 patient study. Remember I showed you that article? 22 A. Oh, I'm sorry. 23 Q. And that article calculated that the 24 25 people who needed surgery of the 34 total 25 exposures totaled 73 percent; is that correct?</p>	<p>1 Q. Second column, sir, 25 out of 34 is 2 73 percent, isn't it? 3 A. I do see where it says -- 4 Q. Your company was well aware that it 5 should never represent to doctors that most 6 exposures can be conservatively treated in a 7 successful way because your company knew that when 8 Dr. Cosson and his group reported their data, they 9 reported that 73 percent of the exposures required 10 surgery. Correct? 11 A. Can I have a moment to finish reading 12 this, because this is a different section than we 13 referred to previously? 14 MR. BROWN: Go ahead and answer the 15 question he's got. And if you need to relook at 16 something, you can. 17 THE WITNESS: I'm having difficulty 18 answering the question, because I don't -- I do see 19 the 73 percent, but I don't -- I haven't -- I can't 20 understand what they're referring to as 73 percent. 21 BY MR. SLATER: 22 Q. They're referring to 25 out of 34 23 equals 73 percent. It's 34 total exposures, 25 24 needed surgery, that's 73 percent of the exposures 25 needing surgery. But you can certainly look further</p>
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<p>1 A. Could I -- I'd like to bring the 2 article in front of me -- 3 Q. You can look right in the abstract. 4 A. -- to confirm what you're asking me. 5 Q. Go right to the abstract on the first 6 page. 7 A. I'm sorry. 8 I'd like to answer the question as 9 accurately as possible. 10 Q. That's fine. You can confirm as to 11 whether or not I'm right that they said 73 percent 12 of the exposures required surgery. 13 You see the 73 percent? 14 A. I don't. Can you show me? I don't 15 see it in the abstract. Can you show me where 16 you're looking in the abstract? 17 Q. If you hand me the article so I don't 18 have to find it in my pile, I'll hand it to you. 19 A. Sure. 20 Q. It's actually in the "Results" 21 section and it's in a few other places, but you can 22 look right here halfway down, you'll see it's 23 73-point-something percent. 24 A. In the first column or the second 25 column?</p>	<p>1 if you want to confirm that. 2 A. Thank you for letting me finish 3 reading the document. I do see the 73 percent. 4 Q. I'm going to hand you an article 5 marked as T-1055. It's been marked as another 6 exhibit on previous occasions, but we're not going 7 to fish for that. 8 This is an article by -- 9 A. This one wasn't marked. 10 MR. BROWN: Here. 11 - - - 12 (Deposition Exhibit No. T-1055, 13 Article entitled "Transvaginal repair of 14 genital prolapse: preliminary results of 15 a new tension-free vaginal mesh (Prolift 16 technique) -- a case series multicentric 17 study," by B. Fatton, et al., Bates 18 stamped ETH-02358 through ETH-02367, was 19 marked for identification.) 20 - - - 21 BY MR. SLATER: 22 Q. This is an article by Fatton, 23 F-A-T-T-O-N, et cetera, including Cosson, Amblard, 24 Debodinance and Jacquetin. Do you see this? Do you 25 see the article in front of you, 2006?</p>

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<p>1 A. Yes. I'm just taking a moment to</p> <p>2 read the title. This -- I don't recall seeing this</p> <p>3 yesterday.</p> <p>4 Q. What I'm going to do is I'm going to</p> <p>5 draw your attention now to the page towards the end</p> <p>6 of the 2007, as you've called it, professional ed</p> <p>7 deck for the Prolift -- Gynecare Prolift system,</p> <p>8 early outcome data.</p> <p>9 Do me a favor, if you could, and turn</p> <p>10 to that page also, because this article is being</p> <p>11 quoted on that page. I want to ask you a couple of</p> <p>12 questions.</p> <p>13 A. I'm sorry, where are you looking?</p> <p>14 Q. This is the slide -- the professional</p> <p>15 ed slide deck, it's a page that you went through a</p> <p>16 few minutes ago.</p> <p>17 A. From 2005?</p> <p>18 Q. 2007. The page that says, "Early</p> <p>19 Outcome Data" for the Prolift.</p> <p>20 A. And it's towards the back?</p> <p>21 Q. Towards the back. There's a list of</p> <p>22 studies. Got it?</p> <p>23 A. I believe I'm looking at the same</p> <p>24 slide that you are.</p> <p>25 Q. Okay.</p>	<p>1 Q. One of them is "Granuloma." Right?</p> <p>2 A. "Granuloma (without exposure.)"</p> <p>3 Q. Right.</p> <p>4 And is that listed on the list of</p> <p>5 complications that were reported in this study on</p> <p>6 the professional ed deck?</p> <p>7 A. I don't see that. However, the</p> <p>8 information --</p> <p>9 Q. Sir --</p> <p>10 A. -- in the slide deck would be a</p> <p>11 summary of this article as opposed to being --</p> <p>12 MR. SLATER: Move to strike.</p> <p>13 THE WITNESS: -- comprehensive of</p> <p>14 everything that's in this entire article.</p> <p>15 MR. SLATER: Move to strike.</p> <p>16 BY MR. SLATER:</p> <p>17 Q. Is there -- well, rephrase.</p> <p>18 In Table 6 the first complication</p> <p>19 listed is "Granuloma (without exposure),"</p> <p>20 2.8 percent.</p> <p>21 Is that complication listed on the</p> <p>22 table in the professional ed deck? Does that appear</p> <p>23 there, yes or no?</p> <p>24 A. I don't see that, but the reference</p> <p>25 is listed here if a surgeon wanted to get that</p>
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<p>1 Looking at the second Prolift</p> <p>2 professional education slide deck, I'm on the page</p> <p>3 that says, Prolift "Early Outcome data." And if you</p> <p>4 look, there's a list of studies.</p> <p>5 And the second study listed is</p> <p>6 Fatton, et al., 110 patients and then some</p> <p>7 information is provided. Right? Do you see that?</p> <p>8 A. I do see that, yes.</p> <p>9 Q. And obviously it was required that</p> <p>10 this information be accurate and complete and fair</p> <p>11 and balanced in representing the significant</p> <p>12 information in the article. Right?</p> <p>13 A. That's my understanding, yes.</p> <p>14 Q. And I've handed you the actual</p> <p>15 article as Exhibit T-1055.</p> <p>16 You have that to your left now.</p> <p>17 Right?</p> <p>18 A. Yes.</p> <p>19 Q. What I'd like you to do now is turn</p> <p>20 to the page that has the Bates number at the bottom</p> <p>21 02364. In the bottom right is Table 6,</p> <p>22 "Post-operative adverse events at 3 months."</p> <p>23 You see the little table there that</p> <p>24 lists some of the complications?</p> <p>25 A. I do, yes.</p>	<p>1 document.</p> <p>2 MR. SLATER: Move to strike from</p> <p>3 "but" forward.</p> <p>4 MR. BROWN: If he's asking you is it</p> <p>5 the actual data on there, just yes or no.</p> <p>6 THE WITNESS: Sure.</p> <p>7 BY MR. SLATER:</p> <p>8 Q. And I'm going to ask it clean again,</p> <p>9 because I don't feel like having to edit all my</p> <p>10 questions and spend a lot of money on my tech guys,</p> <p>11 so I'm going to ask it again.</p> <p>12 In Table 6 it says "Granuloma</p> <p>13 (without exposure)," 2.8 percent of the people in</p> <p>14 the study.</p> <p>15 Is that complication, "granuloma</p> <p>16 (without exposure)," listed on the list of</p> <p>17 complications on the prof ed deck for this article?</p> <p>18 Does it appear there?</p> <p>19 A. I don't see it as I sit here today.</p> <p>20 Q. The next one says, "Mesh exposure,"</p> <p>21 4.7 percent.</p> <p>22 Is that listed on the list of</p> <p>23 complications in the prof ed deck?</p> <p>24 A. Yes.</p> <p>25 Q. Well, I see cystotomy, hematoma and</p>

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<p>1 voiding dysfunction. You're telling me you see mesh 2 exposure for the Fatton article? 3 A. I do, yes. It's the next column to 4 the right. 5 Q. Ah, okay. You're right. I stand 6 corrected. Okay. 7 On Table 6, the postoperative adverse 8 events for the Fatton study, "Shrinkage of mesh," 9 which would also be mesh contraction. Correct? 10 A. I defer that to medical affairs. 11 Q. You don't know that shrinkage and 12 contraction are synonymous terms? 13 A. I only know what I would have 14 heard -- 15 Q. You confirmed it yesterday. 16 A. -- from medical doctors -- 17 Q. You confirmed it yesterday to me that 18 contraction, shrinkage and retraction are the same 19 thing. 20 Did you -- 21 Have you lost track of that since 22 yesterday? 23 A. I haven't lost track of it since 24 yesterday. I don't recall saying -- confirming that 25 yesterday.</p>	<p>1 Is that listed as one of the 2 complications? 3 A. I don't know what vaginal synechia 4 is. 5 Q. Well, it's not listed, is it? 6 A. I don't see those words listed on 7 this slide, but it could be -- I defer that to 8 medical affairs. 9 Q. Shrinkage of mesh is a significant 10 issue with the Prolift. Correct? 11 MR. BROWN: Objection. 12 THE WITNESS: No. 13 BY MR. SLATER: 14 Q. Rephrase. 15 Did you know, by the way -- rephrase. 16 Well, I'll ask the question clean. 17 Were you ever aware or was 18 professional education ever aware that medical 19 affairs had serious concerns about the erosion and 20 contraction/shrinkage rates with the mesh material, 21 the Gynemesh PS mesh material in the Prolift? 22 A. I was not aware of that. 23 Q. Was professional education at Ethicon 24 ever aware that starting almost two years before the 25 Prolift was even launched, that the French doctors</p>
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<p>1 Q. Do you know as you sit here now that 2 contraction, retraction and shrinkage are 3 interchangeable synonymous terms? 4 A. I would defer that to medical 5 affairs. I don't have -- 6 Q. What's your understanding? 7 A. My understanding is that they 8 describe a similar type of situation that a medical 9 doctor would use to describe something. 10 Q. On Table 6, postoperative adverse 11 events in the Fatton article, it lists "Shrinkage of 12 mesh," 18 patients, which was 17 percent of them. 13 Do you see that? 14 A. Yes. 15 Q. In the professional ed deck 16 summarizing the complications from that study, is 17 shrinkage of mesh listed? 18 A. I don't see it on this slide. 19 Q. Are the terms contraction or 20 retraction of mesh listed? 21 A. I don't see it on this slide. 22 Q. On Table 6, it's the list of 23 postoperative adverse events, "Vaginal synechia," 24 S-Y-N-E-C-H-I-A, that one patient had that 25 condition.</p>	<p>1 who were in the TVM Group were asking your company 2 to come up with a safer, better mesh material 3 because they were concerned about the rates and 4 severity of erosion and contraction? 5 MR. BROWN: Objection. 6 BY MR. SLATER: 7 Q. Were you -- 8 Was your department aware of that? 9 MR. BROWN: Objection. 10 THE WITNESS: We wouldn't have been 11 aware of something that was -- 12 BY MR. SLATER: 13 Q. It's just a yes or no question. 14 Were you aware or not? 15 A. No, we weren't aware two years before 16 the product was launched. 17 Q. In fact, professional education was 18 never aware that medical affairs had been told by 19 the French doctors they needed to work to find a 20 better mesh material than Gynemesh PS because of the 21 issues with erosion and contraction. Your 22 department never knew that. Right? 23 MR. BROWN: Objection. 24 THE WITNESS: I can't agree to that. 25 I don't know what was told to my department in the</p>

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<p>1 time that I wasn't --</p> <p>2 BY MR. SLATER:</p> <p>3 Q. As far as you know, was that ever</p> <p>4 told?</p> <p>5 A. As far as I know, I don't recall that</p> <p>6 being discussed. But it may very well have been</p> <p>7 discussed with somebody else in professional</p> <p>8 education.</p> <p>9 Q. Now, go to the very first page of the</p> <p>10 article.</p> <p>11 Not that, the article, the Fatton</p> <p>12 article, the actual published article.</p> <p>13 Very end of the abstract on the first</p> <p>14 page, the last sentence says, "Anatomical and</p> <p>15 functional results must be assessed with a long-term</p> <p>16 follow-up to confirm the effectiveness and safety of</p> <p>17 the procedure."</p> <p>18 Is that information conveyed with</p> <p>19 regard to the Fatton article that is summarized here</p> <p>20 in this professional education deck, the second</p> <p>21 deck, that those authors said that they needed to do</p> <p>22 long-term studies to confirm that the Prolift</p> <p>23 procedure is safe and effective?</p> <p>24 A. I think that that was something that</p> <p>25 was conveyed.</p>	<p>1 Q. The fact that 17 percent shrinkage</p> <p>2 rate in the 110-patient study by Fatton, Cosson,</p> <p>3 Jacquetin, et al., was not disclosed in this summary</p> <p>4 that's provided in the professional ed deck renders</p> <p>5 the summary of that article not fair and balanced.</p> <p>6 Correct?</p> <p>7 MR. BROWN: Objection.</p> <p>8 THE WITNESS: No, I can't agree with</p> <p>9 that.</p> <p>10 BY MR. SLATER:</p> <p>11 Q. You can't agree or do you need to ask</p> <p>12 medical affairs?</p> <p>13 A. I would defer the question to medical</p> <p>14 affairs.</p> <p>15 MR. SLATER: Assuming that counsel is</p> <p>16 not going to requestion you again, I would think I'm</p> <p>17 done.</p> <p>18 MR. BROWN: Can we take --</p> <p>19 MR. SLATER: But I will say, just for</p> <p>20 the record, that we're going to be making requests</p> <p>21 for these webcasts, the telesurgeries, the videos,</p> <p>22 the transcripts, everything, to make sure that we</p> <p>23 have it all. If we do, awesome. If we don't, I'm</p> <p>24 going to reserve my rights with regard to that issue</p> <p>25 and the other questions I am -- the other issues</p>
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<p>1 Q. Show me where on the document. I'm</p> <p>2 not asking you in the stratosphere. I'm asking you</p> <p>3 here in the document, is that information conveyed</p> <p>4 that those authors of that article had that</p> <p>5 conclusion?</p> <p>6 A. That's a pretty typical conclusion</p> <p>7 that appears in most clinical studies.</p> <p>8 MR. SLATER: Sir, I move to strike.</p> <p>9 I move to strike.</p> <p>10 BY MR. SLATER:</p> <p>11 Q. Did I ask you, with all due respect,</p> <p>12 whether it's a typical conclusion? Did I ask you</p> <p>13 that?</p> <p>14 A. I'm not certain.</p> <p>15 Q. You're not certain if I just asked</p> <p>16 you whether that's a typical conclusion?</p> <p>17 MR. BROWN: If he's asking you if</p> <p>18 that language is in the slide deck, answer if that</p> <p>19 language is in the slide deck or not in the slide</p> <p>20 deck.</p> <p>21 THE WITNESS: Thank you. That's</p> <p>22 clear.</p> <p>23 That language I don't see in the</p> <p>24 slide deck as I sit here today.</p> <p>25 BY MR. SLATER:</p>	<p>1 we're going to write to you about. I don't think</p> <p>2 we're going to need to requestion this witness, but</p> <p>3 I have to see what we get, if it's material we</p> <p>4 didn't have. Other than that, we're done.</p> <p>5 MR. BROWN: Are you going to follow</p> <p>6 that with a letter?</p> <p>7 MR. SLATER: Absolutely. You'll get</p> <p>8 a detailed letter.</p> <p>9 MR. BROWN: Okay. I don't have any</p> <p>10 questions. Can we take a break?</p> <p>11 THE VIDEOGRAPHER: The time is now</p> <p>12 11:19. This is the end of Disk Number 1. We are</p> <p>13 going off the record.</p> <p>14 - - -</p> <p>15 (A recess was taken from 11:19 a.m.</p> <p>16 to 11:34 a.m.)</p> <p>17 - - -</p> <p>18 THE VIDEOGRAPHER: The time is now</p> <p>19 11:34. This is the beginning of Disk Number 2. We</p> <p>20 are back on the record.</p> <p>21 - - -</p> <p>22 EXAMINATION</p> <p>23 - - -</p> <p>24 BY MR. AYLSTOCK:</p> <p>25 Q. Hello, Mr. Parisi. My name is Brian</p>

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<p>1 Aylstock.</p> <p>2 We met yesterday; is that correct?</p> <p>3 A. Yes.</p> <p>4 Q. The rules --</p> <p>5 The deposition is continuing, but do</p> <p>6 you understand that you're still under oath?</p> <p>7 A. Yes.</p> <p>8 Q. And the same rules that Mr. Slater</p> <p>9 went over you apply with me; is that right?</p> <p>10 A. Yes.</p> <p>11 Q. So let me show you what was</p> <p>12 previously marked in your earlier deposition as</p> <p>13 Exhibit 123.</p> <p>14 Is that your CV?</p> <p>15 A. Yes, this looks like my CV. I don't</p> <p>16 know that this is the most current version.</p> <p>17 Q. Well, you wrote this document; is</p> <p>18 that right?</p> <p>19 A. I did, yes.</p> <p>20 Q. And it's important to you that a</p> <p>21 curriculum vitae or CV is accurate; is that right?</p> <p>22 A. Yes.</p> <p>23 Q. Do you believe it to be accurate?</p> <p>24 A. I do, yes.</p> <p>25 Q. Let me ask you a few questions.</p>	<p>1 A. I held it for -- at one point in</p> <p>2 time. It wasn't equivalent to the role that my</p> <p>3 boss's boss currently holds.</p> <p>4 Q. When did that change take place, you</p> <p>5 said about a year ago?</p> <p>6 A. Yes.</p> <p>7 Q. Why did that happen?</p> <p>8 A. The company went through some</p> <p>9 restructuring, and my job was eliminated at the</p> <p>10 time. And I interviewed for the job that I</p> <p>11 currently have.</p> <p>12 Q. So in essence, you're now</p> <p>13 reporting -- well, strike that.</p> <p>14 You were demoted; is that right?</p> <p>15 A. No.</p> <p>16 Q. No.</p> <p>17 Regional professional education</p> <p>18 manager is equivalent to director of professional</p> <p>19 education worldwide in the hierarchy of Ethicon?</p> <p>20 A. I wouldn't say it's equivalent, but I</p> <p>21 wouldn't say I was demoted. I described the</p> <p>22 situation of the company went through restructuring,</p> <p>23 which is not uncommon in today's economy. My job at</p> <p>24 the time of director of professional education</p> <p>25 worldwide was eliminated, and I was able to</p>
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<p>1 I think you just testified that</p> <p>2 you're now a regional PE manager or are you still</p> <p>3 director of professional education worldwide?</p> <p>4 A. I'm a regional professional education</p> <p>5 manager currently.</p> <p>6 Q. When did that change happen?</p> <p>7 A. About a year ago.</p> <p>8 Q. Now, in the hierarchy, a regional</p> <p>9 professional education would be -- would report to</p> <p>10 the director of professional education worldwide; is</p> <p>11 that right?</p> <p>12 A. That's correct. Not to worldwide. I</p> <p>13 report currently to the director of professional</p> <p>14 education in the US.</p> <p>15 Q. And that director of professional</p> <p>16 education in the US is who?</p> <p>17 A. Tom Affeld.</p> <p>18 Q. And Tom Affeld as director of</p> <p>19 professional education US would report to director</p> <p>20 of professional education worldwide; is that</p> <p>21 correct?</p> <p>22 A. I believe so, yes.</p> <p>23 Q. So, but at one point, you held</p> <p>24 director of professional education worldwide; is</p> <p>25 that correct?</p>	<p>1 interview and successfully gain the job that I</p> <p>2 currently hold.</p> <p>3 Q. Well, somebody holds this position</p> <p>4 now, director of professional education worldwide.</p> <p>5 Who is that?</p> <p>6 A. Not for Ethicon Women's Health &</p> <p>7 Urology. That division of -- is no longer a</p> <p>8 division of Ethicon.</p> <p>9 Q. What is it a division of?</p> <p>10 A. It's no longer a company.</p> <p>11 Q. Well, I thought you said that your</p> <p>12 boss reported to director of professional education</p> <p>13 worldwide.</p> <p>14 Is that with another Johnson &</p> <p>15 Johnson company?</p> <p>16 A. With Ethicon.</p> <p>17 Q. With Ethicon.</p> <p>18 Did you apply for that position</p> <p>19 within Ethicon?</p> <p>20 A. Which position?</p> <p>21 Q. Director of professional education</p> <p>22 worldwide, the same position you had for Ethicon's</p> <p>23 Women's Health & Urology?</p> <p>24 A. I did, yes.</p> <p>25 Q. You didn't get that position?</p>

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<p>1 A. I didn't get that position. Correct.</p> <p>2 Q. You didn't get the director of</p> <p>3 professional education US either, did you?</p> <p>4 A. That's correct.</p> <p>5 Q. You applied for both of those</p> <p>6 simultaneously, or was there a process?</p> <p>7 A. I believe it was both simultaneously.</p> <p>8 Q. What was the individual's name who</p> <p>9 got the director of professional education US?</p> <p>10 A. Tom Affeld.</p> <p>11 Q. How do you spell that?</p> <p>12 A. A-F-F-E-L-D.</p> <p>13 Q. Does he have responsibility for the</p> <p>14 TVT line of products for Ethicon?</p> <p>15 A. Yes.</p> <p>16 Q. Currently?</p> <p>17 A. Amongst other things, yes.</p> <p>18 Q. And you have regional responsibility</p> <p>19 for those products currently?</p> <p>20 A. Yes. For professional education.</p> <p>21 Q. And what is your region?</p> <p>22 A. My region is basically the states</p> <p>23 between Maine and Minnesota down south on the</p> <p>24 western border to Tennessee and on the eastern</p> <p>25 border to New York state.</p>	<p>1 products are products under the Ethicon Surgical</p> <p>2 Care division.</p> <p>3 Q. So you went to work for Johnson &</p> <p>4 Johnson/Ethicon right out of college. Right?</p> <p>5 A. Yes.</p> <p>6 Q. In fact, they paid for your</p> <p>7 scholarship to Brazil, didn't they?</p> <p>8 A. That was well before I was involved.</p> <p>9 I applied for a scholarship in, I believe it was</p> <p>10 1985, before I even attended college. And it was a</p> <p>11 very competitive process, and I won a scholarship to</p> <p>12 do a student exchange to Brazil for two months.</p> <p>13 Subsequent to that, I went to college. And upon</p> <p>14 graduating college, I applied for a position within</p> <p>15 the Ethicon division. And I succeeded in getting</p> <p>16 that position.</p> <p>17 Q. So J&J paid for part of your college.</p> <p>18 Right?</p> <p>19 A. No.</p> <p>20 Q. They paid for the full scholarship to</p> <p>21 Brazil, according to your resume; is that --</p> <p>22 A. They paid for the scholarship before</p> <p>23 I went to college. I was a high school student and</p> <p>24 I applied for a scholarship because I wanted to do a</p> <p>25 student exchange. Johnson & Johnson had that</p>
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<p>1 Q. Is there a number for your region or</p> <p>2 nomenclature, region A, region 1?</p> <p>3 A. North Central Region.</p> <p>4 Q. How many regional managers are there</p> <p>5 in the US?</p> <p>6 A. Three.</p> <p>7 Q. Who are the other two?</p> <p>8 A. Cathy Jarczynski.</p> <p>9 Q. How do you spell Jarczynski?</p> <p>10 A. J-A-R-C-Z-Y-N-S-K-I.</p> <p>11 Q. And the other one?</p> <p>12 A. Rick Lombardi.</p> <p>13 Q. How have your responsibilities</p> <p>14 changed now that you're regional PE manager instead</p> <p>15 of the director for professional education</p> <p>16 worldwide?</p> <p>17 A. I'm responsible for regional</p> <p>18 professional education for the Ethicon Surgical Care</p> <p>19 division and the Ethicon Energy division within</p> <p>20 those states that I previously described.</p> <p>21 Q. And the Ethicon Women's Care would</p> <p>22 include the TVT portfolio of products?</p> <p>23 A. There is no longer Ethicon Women's</p> <p>24 Care. The companies that I currently support are</p> <p>25 Ethicon Surgical Care and Ethicon Energy. The TVT</p>	<p>1 scholarship available, and there was a competitive</p> <p>2 process that I was able to win that scholarship.</p> <p>3 And they paid for the expenses for me to do that</p> <p>4 student exchange when I was in -- when I just</p> <p>5 graduated from high school and before I started</p> <p>6 college. I've not received any other scholarships</p> <p>7 or anything from Johnson & Johnson, nor did that</p> <p>8 have any relationship to my later employment with</p> <p>9 Johnson & Johnson.</p> <p>10 Q. Well, I guess my point is, you've</p> <p>11 never worked for any other company other than</p> <p>12 Johnson & Johnson/Ethicon?</p> <p>13 A. I worked for the Princeton Review</p> <p>14 before I came to Johnson & Johnson.</p> <p>15 Q. Was that before college or during</p> <p>16 college?</p> <p>17 A. That was during college.</p> <p>18 Q. So since you graduated from Rutgers</p> <p>19 with a mechanical engineering degree, you have only</p> <p>20 worked for Johnson & Johnson companies; is that</p> <p>21 correct?</p> <p>22 A. That's correct.</p> <p>23 Q. Never had any other employment?</p> <p>24 A. That's correct.</p> <p>25 Q. And so that's been 23 years?</p>

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<p>1 A. It's 22, I believe, in October.</p> <p>2 Q. 22 years? Okay.</p> <p>3 You started as a product development</p> <p>4 engineer; is that right?</p> <p>5 A. Yes.</p> <p>6 Q. And then you ended up as a clinical</p> <p>7 sales representative and a field sales trainer?</p> <p>8 A. Yes.</p> <p>9 Q. So you for a period of time at</p> <p>10 Ethicon were a sales rep, meeting with doctors; is</p> <p>11 that right?</p> <p>12 A. That's right.</p> <p>13 Q. And then you went into marketing.</p> <p>14 Right?</p> <p>15 A. I did, yes.</p> <p>16 Q. And you became product director.</p> <p>17 Correct?</p> <p>18 A. I was first in marketing, new product</p> <p>19 strategic marketing manager between 2001 and 2003.</p> <p>20 And then in 2003, I became product director.</p> <p>21 Q. So let's look at the new product</p> <p>22 strategic -- strategic marketing manager, the CV</p> <p>23 says from September '01 to January '03; is that</p> <p>24 right?</p> <p>25 A. That's correct.</p>	<p>1 our research and development process for products</p> <p>2 that were used in those specialties.</p> <p>3 Q. It says also, "Chartered new business</p> <p>4 venture into pelvic floor repair including</p> <p>5 multigenerational marketing model to succeed into</p> <p>6 the pipeline for five-plus years."</p> <p>7 What does that mean?</p> <p>8 A. That just describes one of the</p> <p>9 projects that I worked on. The pelvic floor repair</p> <p>10 area was something that -- this job involved me</p> <p>11 working on the Gynemesh PS project. I may also have</p> <p>12 had some involvement with the TVM project as well.</p> <p>13 Q. You point out the annual sales</p> <p>14 revenue of those exceeded \$100 million; is that</p> <p>15 right?</p> <p>16 A. I believe so, yes.</p> <p>17 Q. So this is a marketing position.</p> <p>18 Correct?</p> <p>19 A. I reported to R&D. It was a liaison</p> <p>20 position between R&D and marketing.</p> <p>21 Q. It was a marketing position.</p> <p>22 Correct?</p> <p>23 A. I can't agree to that. I reported to</p> <p>24 R&D. The title does include marketing in it.</p> <p>25 Q. Well, it doesn't say anything about</p>
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<p>1 Q. Which products were involved?</p> <p>2 Which -- were there pelvic mesh products involved in</p> <p>3 that position?</p> <p>4 A. I believe the Gynemesh PS was</p> <p>5 involved in that position.</p> <p>6 Q. And TVT-O? TVT Classic?</p> <p>7 A. TVT-O may have also been involved in</p> <p>8 that position as well.</p> <p>9 Q. That was a marketing position?</p> <p>10 A. I actually reported to research and</p> <p>11 development, even though the title says marketing.</p> <p>12 Q. So your title was marketing, but you</p> <p>13 were in the research and development side of things?</p> <p>14 A. That's correct.</p> <p>15 Q. And even in that position, it says</p> <p>16 you partnered with thought leaders in urology,</p> <p>17 urogynecology and gynecology to evaluate new ideas</p> <p>18 and refine them into well-designed, successful new</p> <p>19 procedures in incontinence and pelvic floor.</p> <p>20 Can you tell me what that means?</p> <p>21 A. That just refers to the type of</p> <p>22 projects that I worked on between 2001 and 2003. I</p> <p>23 worked with -- in this R&D function, I worked with</p> <p>24 surgeons who were urologists, urogynecologists and</p> <p>25 gynecologists, to gain their input and feedback in</p>	<p>1 R&D, does it?</p> <p>2 A. I don't see R&D listed here, but I am</p> <p>3 telling you today that despite that information not</p> <p>4 being here, this was an R&D position. And that's</p> <p>5 available in my personnel records as well.</p> <p>6 Q. You don't disagree that this position</p> <p>7 involved the marketing of those products, do you?</p> <p>8 A. I don't disagree at all. I said it</p> <p>9 was a liaison between marketing and research and</p> <p>10 development.</p> <p>11 Q. Then you became product director in</p> <p>12 January of '03; is that right?</p> <p>13 A. Yes.</p> <p>14 Q. Product director is a marketing</p> <p>15 position exclusively. Correct?</p> <p>16 A. That is a marketing position.</p> <p>17 Correct.</p> <p>18 Q. It looks like in this position you</p> <p>19 managed the \$50 million tension-free vaginal tape</p> <p>20 TVT business during onset of highly competitive</p> <p>21 market. Do you see that?</p> <p>22 A. Yes.</p> <p>23 Q. What does that mean?</p> <p>24 A. That means I managed the TVT business</p> <p>25 from a marketing perspective in that period between</p>

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<p>1 2003 and February of 2005.</p> <p>2 Q. Now, TVT stands for tension-free</p> <p>3 vaginal tape; is that right?</p> <p>4 A. That's correct.</p> <p>5 Q. And that's been what it stood for</p> <p>6 since the very beginning, to your knowledge.</p> <p>7 Correct?</p> <p>8 A. Yes.</p> <p>9 Q. And that's widely known within the</p> <p>10 company?</p> <p>11 A. I believe so. I can't attest to what</p> <p>12 other people know or don't know, but I can tell you</p> <p>13 that's my understanding of what TVT means.</p> <p>14 Q. And that was your understanding when</p> <p>15 you were working as a product development engineer,</p> <p>16 or do you recall?</p> <p>17 A. I had no involvement with TVT between</p> <p>18 those years that I was a product development</p> <p>19 engineer.</p> <p>20 Q. Well, the years you were product</p> <p>21 director, the TVT was experiencing declining market</p> <p>22 share; is that right?</p> <p>23 A. Yes.</p> <p>24 Q. And you helped to turn around that</p> <p>25 declining market share; is that right?</p>	<p>1 different TVT products.</p> <p>2 Q. Is the original in your nomenclature</p> <p>3 described as the TVT Classic?</p> <p>4 A. Yes.</p> <p>5 Q. And then there's TVT-O for the</p> <p>6 transobturator; is that right?</p> <p>7 A. There's also TVT abdominal or TVT</p> <p>8 with abdominal guides.</p> <p>9 Q. Is that TVT-AA?</p> <p>10 A. I'm not sure. I haven't used the</p> <p>11 term, but it -- what -- the product that from my</p> <p>12 knowledge is termed is TVT with abdominal guides.</p> <p>13 Q. Okay.</p> <p>14 And then there's TVT SECUR or TVT-S;</p> <p>15 is that right?</p> <p>16 A. Yes.</p> <p>17 Q. And TVT EXACT?</p> <p>18 A. Yes.</p> <p>19 Q. And TVT ABBREVO?</p> <p>20 A. Yes.</p> <p>21 Q. Okay.</p> <p>22 You were --</p> <p>23 Were you product director over TVT-S</p> <p>24 or was that after your time?</p> <p>25 A. That was after my time in marketing.</p>
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<p>1 A. Yes.</p> <p>2 Q. And there's also declining unit sales</p> <p>3 and flat revenue. Correct?</p> <p>4 A. Yes.</p> <p>5 Q. For the TVT product?</p> <p>6 A. Yes. In that time period.</p> <p>7 Q. And it also, as product director,</p> <p>8 marketing position at the bottom, says you launched</p> <p>9 Ethicon's first direct-to-consumer patient education</p> <p>10 PR campaign featuring Olympic speed skater Bonnie</p> <p>11 Blair; is that right?</p> <p>12 A. That's correct.</p> <p>13 MR. BROWN: Bryan, let me just ask</p> <p>14 you this. When you just used the word "TVT," is</p> <p>15 that just going to refer to the retropubic or</p> <p>16 Classic?</p> <p>17 MR. AYLSTOCK: Well --</p> <p>18 MR. BROWN: And you did do that</p> <p>19 there, but I just wanted to make sure. I don't --</p> <p>20 if that's our understanding, I'm not going to object</p> <p>21 to different things, but...</p> <p>22 BY MR. AYLSTOCK:</p> <p>23 Q. Well, how many TVT products are</p> <p>24 there?</p> <p>25 A. There are I think about five</p>	<p>1 Q. Well, I think if it's okay with you,</p> <p>2 when I refer to TVT, I'm asking you about TVT</p> <p>3 Classic. And if I ask a question about TVT-O, I'll</p> <p>4 ask about that or TVT-S would be SECUR. If I talk</p> <p>5 about the TVT products, what I'm talking about is</p> <p>6 the entire range of products. Is that fair?</p> <p>7 A. The only question I would have is</p> <p>8 where would you put the TVT with abdominal guides?</p> <p>9 Q. I would put them as one of the TVT</p> <p>10 products.</p> <p>11 Is that a fair characterization?</p> <p>12 A. Yes, that's fair. As long as you use</p> <p>13 those descriptions, I'll be able to answer your</p> <p>14 questions as accurately as I can.</p> <p>15 Q. I appreciate that.</p> <p>16 Bullet point number 4 talks about how</p> <p>17 you launched Gynemesh PS and the TVT obturator</p> <p>18 system. Do you see that?</p> <p>19 A. Yes.</p> <p>20 Q. So what do you mean by launched those</p> <p>21 two products?</p> <p>22 A. I was involved when the products were</p> <p>23 launched. There were other team members that were</p> <p>24 also involved when those products were launched.</p> <p>25 But during the time period that I held the position</p>

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<p>1 of product director, the Gynemesh PS and the TVT 2 obturator system were launched, meaning that they 3 were released for sale by the company. 4 Q. And it says, content development and 5 delivery of sales training and professional 6 education. Do you see that? 7 A. Yes, I do see that. 8 Q. So you were involved in content 9 development for professional education as product 10 director, marketing. Correct? 11 A. I was amongst the team of people that 12 were involved, yes, as I've stated before. 13 Q. So what was your involvement in 14 developing the content for the professional 15 education for the TVT-O system? 16 A. In this particular position and this 17 particular time, I represented one of the marketing 18 functions on that team. That team would have also 19 included medical affairs, our preceptors, our 20 surgeons that teach the product, regulatory, legal, 21 quality amongst other groups. So it was a 22 cross-functional team that worked on the content 23 development that's described in that bullet. And I 24 was a member of that team. 25 Q. Yesterday you testified, and I wrote</p>	<p>1 they're one of the people that would nominate 2 surgeons for training and then continue to represent 3 and help the surgeons reach back out to the faculty 4 or the preceptors. 5 Q. Do you agree with me that sales reps 6 shouldn't be the ones training physicians? 7 A. In professional education, surgeons 8 were training physicians. 9 MR. AYLSTOCK: Move to strike. 10 BY MR. AYLSTOCK: 11 Q. I'm asking you -- and we can go round 12 and round like you did earlier today and yesterday. 13 I want you to listen to my question. 14 A. Sure. 15 Q. My question is, should sales reps be 16 training physicians in Ethicon on how to insert or 17 patient selection criteria for any of the TVT 18 products, yes or no? 19 A. No. Sales reps were not training 20 physicians. Surgeons were training physicians. 21 MR. BROWN: Do me a favor. Give me 22 one second. 23 If he's asking you if sales reps 24 should be training them, just answer yes or no. 25 Don't add the next part, which is the doctors are</p>
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<p>1 it down, that the intent of professional education 2 is to provide training in safe and effective use of 3 your products. Do you recall that testimony? 4 A. Yes. I do recall that, yes. 5 Q. Do you agree with -- 6 Today you still agree that that's the 7 intent of professional education? 8 A. I do agree that that's the intent of 9 professional education. 10 Q. You would agree with me that 11 professional education shouldn't have anything to do 12 with sales. Sales shouldn't drive professional 13 education, should it? 14 A. Sales is involved in professional 15 education. As a business, one of the outcomes of 16 sales is to drive revenue. That revenue pays for 17 things that the company does in support of its 18 products and in support of research and development 19 and future innovation. So I would say that sales 20 would be a part of professional education. 21 Q. Okay. 22 So it's your testimony that 23 professional education should involve the sales of 24 the product? 25 A. It does involve the salespeople, and</p>	<p>1 doing the training. 2 THE WITNESS: Sure, I'm sorry. 3 MR. BROWN: Just yes or no on his 4 question. 5 THE WITNESS: Okay. I apologize. 6 MR. AYLSTOCK: Move to strike the 7 answer and I'll ask it clean. 8 MR. BROWN: Sure. 9 BY MR. AYLSTOCK: 10 Q. Should sales reps be training 11 physicians on how to perform the TVT surgery of any 12 of the products or what patients should be selected? 13 Is that a sales rep function? 14 A. I don't see that as a sales rep 15 function as I sit here today. 16 Q. It would be improper if that 17 happened. Correct? 18 A. I can't say that it would be 19 improper. I never was involved in the sales 20 department for TVT. 21 Q. As a professional education director, 22 you can't tell this jury one way or the other 23 whether sales reps training physicians would be 24 improper? 25 A. Sales reps -- I think I answered</p>

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<p>1 that -- do not train physicians on use of the</p> <p>2 product.</p> <p>3 MR. AYLSTOCK: No, no, no, you</p> <p>4 didn't. Move to strike.</p> <p>5 BY MR. AYLSTOCK:</p> <p>6 Q. I'm asking you as the professional</p> <p>7 education director for the TVT products whether you</p> <p>8 believe that a sales rep training a physician is an</p> <p>9 improper thing for that sales rep to do?</p> <p>10 A. It's my understanding in professional</p> <p>11 education that the training in professional</p> <p>12 education comes from a surgeon, not a sales</p> <p>13 representative.</p> <p>14 Q. It would be wrong for a sales</p> <p>15 representative to be out there training the</p> <p>16 physician on how to perform the surgery because</p> <p>17 sales reps aren't physicians. Right?</p> <p>18 A. Sales reps are not physicians.</p> <p>19 Correct.</p> <p>20 Q. So it would be wrong for a</p> <p>21 nonphysician to be telling a physician how to</p> <p>22 perform the surgery. Correct?</p> <p>23 A. A sales rep may have some involvement</p> <p>24 in guiding a physician or reminding them of the</p> <p>25 information that they received in professional</p>	<p>1 reps shouldn't, in --</p> <p>2 According to Ethicon's policies and</p> <p>3 procedures, sales reps are not supposed to be</p> <p>4 training the doctors on how to perform this</p> <p>5 procedure. Correct?</p> <p>6 A. I would agree that professional</p> <p>7 education is the function in which surgeons provide</p> <p>8 the training on the procedure, yes.</p> <p>9 Q. Okay. So let me ask it again clean.</p> <p>10 Sales reps shouldn't be training</p> <p>11 doctors or physicians, according to Ethicon's</p> <p>12 policies and procedures. Correct?</p> <p>13 A. As I sit here today, I don't know if</p> <p>14 I can give a yes or no answer, because I don't know</p> <p>15 what Ethicon's policies are as they pertain to sales</p> <p>16 representatives.</p> <p>17 Q. As director of professional</p> <p>18 education, your understanding is that it would be</p> <p>19 improper for sales representatives to be in there,</p> <p>20 telling the physicians how to perform the surgery.</p> <p>21 Correct?</p> <p>22 MR. BROWN: Are you asking for</p> <p>23 professional education? I think that might be the</p> <p>24 hiccup with him.</p> <p>25 BY MR. AYLSTOCK:</p>
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<p>1 education. They would not --</p> <p>2 MR. AYLSTOCK: Let me move to</p> <p>3 strike --</p> <p>4 THE WITNESS: -- solely be the person</p> <p>5 that was training the surgeon on the procedure.</p> <p>6 BY MR. AYLSTOCK:</p> <p>7 Q. Listen to my question.</p> <p>8 A. Sure.</p> <p>9 MR. AYLSTOCK: Let me move to strike</p> <p>10 your answer.</p> <p>11 BY MR. AYLSTOCK:</p> <p>12 Q. And we'll get through this faster if</p> <p>13 you listen to my question.</p> <p>14 A. Absolutely. I'm trying my best to do</p> <p>15 that.</p> <p>16 MR. AYLSTOCK: Ann Marie, can you</p> <p>17 read the question back, please?</p> <p>18 - - -</p> <p>19 (The court reporter read the</p> <p>20 pertinent part of the record.)</p> <p>21 - - -</p> <p>22 THE WITNESS: I can't answer that</p> <p>23 with a yes or no.</p> <p>24 BY MR. AYLSTOCK:</p> <p>25 Q. So -- but you would agree that sales</p>	<p>1 Q. Does professional education -- well,</p> <p>2 let me back up.</p> <p>3 You said -- well, let me back way up.</p> <p>4 What is the role of professional</p> <p>5 education within Ethicon?</p> <p>6 A. Professional education provides the</p> <p>7 training by surgeons to surgeons on our products.</p> <p>8 Q. And what was your role as director of</p> <p>9 professional education in providing that training?</p> <p>10 A. Our role was to coordinate the</p> <p>11 logistics around doctors traveling to visit other</p> <p>12 doctors, doctors traveling to hands-on laboratories.</p> <p>13 Our role was also to have been -- to engage with our</p> <p>14 surgeon faculty who would be teaching the products</p> <p>15 to the surgeon learners.</p> <p>16 Q. Is the role of professional education</p> <p>17 to drive revenue for the company?</p> <p>18 A. No.</p> <p>19 Q. That would be improper. Correct?</p> <p>20 A. I wouldn't say that it would be</p> <p>21 improper. It's not the primary goal.</p> <p>22 Q. It's one of the goals?</p> <p>23 A. I would say that as a business, it is</p> <p>24 a possible goal of professional education to -- we</p> <p>25 certainly would want surgeons that we trained to</p>

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<p>1 utilize the products that they were trained on as</p> <p>2 opposed to not utilizing the products. It wouldn't</p> <p>3 be an efficient use of the company's...</p> <p>4 Q. So is one of the goals of</p> <p>5 professional education as well to market the</p> <p>6 product?</p> <p>7 A. No.</p> <p>8 Q. That would be improper?</p> <p>9 MR. BROWN: Objection.</p> <p>10 THE WITNESS: I wouldn't say that</p> <p>11 that would be improper. That's not a goal of</p> <p>12 professional education.</p> <p>13 BY MR. AYLSTOCK:</p> <p>14 Q. And is the -- driving revenue a goal</p> <p>15 of professional education? Is that something</p> <p>16 professional education should be concerned with,</p> <p>17 driving revenue to the company?</p> <p>18 A. Professional education is not in</p> <p>19 the -- is separated from the commercial aspect of</p> <p>20 the business, so I would say that driving revenue is</p> <p>21 not a goal of professional education.</p> <p>22 Q. And it shouldn't be a goal. Correct?</p> <p>23 A. I wouldn't say that it shouldn't be.</p> <p>24 It's important as a business for all functions</p> <p>25 within the business to do their function and also</p>	<p>1 A. I'm familiar with it, yes.</p> <p>2 Q. You've read it?</p> <p>3 A. I've read it, yes.</p> <p>4 Q. You believe in it?</p> <p>5 A. I do, yes.</p> <p>6 Q. You follow it?</p> <p>7 A. Yes.</p> <p>8 Q. Always?</p> <p>9 A. Yes.</p> <p>10 Q. Professional education should always</p> <p>11 be following this, every individual within</p> <p>12 professional education?</p> <p>13 A. Yes.</p> <p>14 Q. Correct?</p> <p>15 And this is the Johnson & Johnson</p> <p>16 credo. Right?</p> <p>17 A. Yes.</p> <p>18 Q. It applies to all the companies owned</p> <p>19 or operated by J&J, including Ethicon and all its</p> <p>20 employees. Correct?</p> <p>21 A. Yes.</p> <p>22 Q. So when we're talking about the J&J</p> <p>23 credo, it's the same as saying the Ethicon credo.</p> <p>24 Correct?</p> <p>25 A. I haven't heard to it referred to as</p>
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<p>1 contribute towards the viability of the company and</p> <p>2 its ability to invest in research and training and</p> <p>3 the production of safe and effective products.</p> <p>4 Q. As an individual who's never had</p> <p>5 another job since college from -- other than at J&J,</p> <p>6 you're familiar with the J&J credo?</p> <p>7 A. Yes, I am.</p> <p>8 Q. Let me show you what's previously</p> <p>9 been marked as Exhibit T-15.</p> <p>10 You probably don't even need to look</p> <p>11 at it, do you?</p> <p>12 A. I'd like to look at it, if you'll</p> <p>13 give me a moment.</p> <p>14 Q. You work in Somerville; is that</p> <p>15 right?</p> <p>16 A. Yes.</p> <p>17 Q. They put this on the wall at</p> <p>18 Somerville, don't they?</p> <p>19 A. I believe so, yes.</p> <p>20 Q. You walk by it every day when you</p> <p>21 come in the office, don't you?</p> <p>22 A. I don't know that I walk by it every</p> <p>23 day, but it's certainly in the hallway.</p> <p>24 Q. Okay.</p> <p>25 And you're familiar with this credo?</p>	<p>1 the Ethicon credo. It's the J&J credo.</p> <p>2 Q. You believe in it and apply -- and</p> <p>3 believe it should be applied in everything every</p> <p>4 employee does within the company. Correct?</p> <p>5 A. Yes, I believe that.</p> <p>6 Q. The first responsibility, according</p> <p>7 to the J&J credo, is what?</p> <p>8 A. The "first responsibility is to...</p> <p>9 doctors, nurses...patients...mothers and fathers and</p> <p>10 all others" that "use our products and services."</p> <p>11 Q. And it also says that mistakes must</p> <p>12 be paid for. Correct?</p> <p>13 A. Yes.</p> <p>14 Q. One of the things that this credo</p> <p>15 stands for is --</p> <p>16 A. I'm sorry, could I just read to</p> <p>17 where -- which section are you referring to? I</p> <p>18 don't want to misspeak as we're looking at a</p> <p>19 specific document.</p> <p>20 Okay. "Research must be carried on,</p> <p>21 innovative programs developed," yes, "and mistakes"</p> <p>22 must be "paid for." I do see that. Thank you.</p> <p>23 Q. And you agree with that?</p> <p>24 A. I do agree with that, yes.</p> <p>25 Q. In essence, what this credo stands</p>

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<p>1 for is that patient safety should come first. 2 Correct? 3 A. Yes. 4 Q. Should come before corporate profits? 5 A. Yes. 6 Q. And your company shouldn't expose 7 anyone, any woman using any of the products, to 8 needless danger for corporate profits. Correct? 9 A. Yes. 10 Q. And in fact, your company should 11 never expose any of the patients that use the 12 products to needless danger, according to this. 13 Correct? 14 A. I'm sorry, can you rephrase the 15 question? 16 Q. Would you agree that the credo stands 17 for the proposition that your company, Ethicon/J&J, 18 should never expose a patient to a needless danger? 19 A. Yes. 20 Q. And that if the -- any -- 21 And that's true for any medical 22 device manufacturer. You believe that. Right? 23 A. I believe that this credo applies to 24 Johnson & Johnson, and that's my understanding of 25 where it's used. I can't speak for another medical</p>	<p>1 would have an interpretation of this as well. 2 BY MR. AYLSTOCK: 3 Q. And as the director of professional 4 education, is that the type of standard that you 5 held yourself to and the employees within 6 professional education to? 7 A. Yes. 8 Q. So the role of professional education 9 in your mind is to train physicians. Correct? 10 A. Yes. 11 Q. And that should be the focus of 12 professional education? 13 A. That is -- yes. That's probably the 14 focus of professional education. Surgeons training 15 surgeons. 16 Q. So let's talk -- you spoke about this 17 in the context of the Prolift and maybe some of the 18 TVT, but let's talk about some of the types of 19 professional education for the TVT line of products. 20 A. Sure. 21 Q. You mentioned hands-on training? 22 A. Yes. 23 Q. Describe that for the jury, please. 24 A. Hands-on training would be the 25 teaching surgeon would demonstrate the proper steps</p>
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<p>1 device manufacturer. 2 Q. All right. 3 Well, you would agree that if there 4 were an instance where Johnson & Johnson or Ethicon 5 failed to put patient safety first and exposed a 6 patient to a needless danger, that it should be 7 accountable for all the harms and losses that result 8 from that. Correct? 9 MR. BROWN: Objection. 10 BY MR. AYLSTOCK: 11 Q. According to this credo? 12 A. Can you rephrase the question, 13 please? 14 Q. If there were an instance where 15 Ethicon or J&J exposed a patient who used one of its 16 products to a needless danger, then it should be 17 held accountable for the harms and losses of the 18 patient that result from exposure of that needless 19 danger. 20 Do you agree with that or disagree 21 with that? 22 MR. BROWN: Objection. 23 THE WITNESS: I would agree that 24 that's what this document says, in my 25 interpretation. There's many people, you know, that</p>	<p>1 in utilizing a product. And the learning surgeon 2 would observe and then be able to perform the 3 training on a hands-on training model. 4 Q. Okay. 5 Is that in the context of a cadaver 6 lab or something like that? 7 A. It could be a cadaver lab or it could 8 be a surgical simulator as well. 9 Q. While we're going through this, it 10 might be helpful just to kind of look at what I 11 marked as Exhibit T-1056. 12 - - - 13 (Deposition Exhibit No. T-1056, 14 Gynecare TVT SECUR System Professional 15 Education Program Opportunities, Consider 16 -- Proper Targeting, Course Effectiveness, 17 & Costs, Bates stamped ETH.MESH.05795106, 18 was marked for identification.) 19 - - - 20 THE WITNESS: Okay, thank you. 21 BY MR. AYLSTOCK: 22 Q. Is this a document you've seen 23 before? 24 A. I believe I've seen it, yes. 25 Q. And these --</p>

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<p>1 Does this list all of the</p> <p>2 professional education materials available for the</p> <p>3 TVT SECUR, or are there others not on this list</p> <p>4 available?</p> <p>5 A. As I sit here today, this seems to be</p> <p>6 a good list of training that was available for TVT</p> <p>7 SECUR.</p> <p>8 Q. In the context of the Prolift, your</p> <p>9 counsel showed you a document with the requirements</p> <p>10 that your company instituted for physicians to use</p> <p>11 the Prolift product.</p> <p>12 Are there similar requirements for</p> <p>13 the TVT line of products?</p> <p>14 A. Yes.</p> <p>15 Q. What are those requirements?</p> <p>16 A. The TVT products were intended for</p> <p>17 use by board certified gynecologists, urologists or</p> <p>18 urogynecologists that treated women with</p> <p>19 incontinence, stress urinary incontinence to be</p> <p>20 specific.</p> <p>21 Q. Were there other requirements or was</p> <p>22 that the only requirement?</p> <p>23 A. Those are the ones I can recall as I</p> <p>24 sit here today.</p> <p>25 Q. So as you sit here today, that was --</p>	<p>1 Q. Well, it's been multiple years.</p> <p>2 Correct?</p> <p>3 A. Yes, it's been multiple years.</p> <p>4 Correct.</p> <p>5 Q. And the only two things that you can</p> <p>6 identify for me are board certified and experience</p> <p>7 in treating patients with stress urinary</p> <p>8 incontinence. Anything else?</p> <p>9 A. I can't recall as I sit here today if</p> <p>10 there was anything else or not.</p> <p>11 Q. If during a break or later on you</p> <p>12 recall something, I'd appreciate you letting your</p> <p>13 counsel know so I can know what your company other</p> <p>14 requirements might have.</p> <p>15 A. Absolutely. I will. Thank you.</p> <p>16 Q. So let's go through this.</p> <p>17 We have the proctorships -- or</p> <p>18 preceptorships. Right?</p> <p>19 A. Yes.</p> <p>20 Q. And the target there is "All surgeons</p> <p>21 who want to learn the procedure." Do you see that?</p> <p>22 A. Yes, I do see that.</p> <p>23 Q. It's "the most effective training</p> <p>24 course available" and it's "the primary option for</p> <p>25 training physicians." Right?</p>
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<p>1 unlike the Prolift procedure which had a number of</p> <p>2 requirements, the only requirement for using a TVT</p> <p>3 product, according to Ethicon, for a physician using</p> <p>4 it, was just to be board certified; is that correct?</p> <p>5 A. I mentioned also in having experience</p> <p>6 treating patients with stress urinary incontinence.</p> <p>7 Q. Anything else?</p> <p>8 A. Without a document in front of me</p> <p>9 like this, it would be hard for me to say. There</p> <p>10 may have been other things.</p> <p>11 Q. You're still in the role of</p> <p>12 professional education on the TVT products today.</p> <p>13 Correct?</p> <p>14 A. Yes, I am.</p> <p>15 Q. And your job is to know what criteria</p> <p>16 are required to train physicians on the product.</p> <p>17 Right?</p> <p>18 A. Yes.</p> <p>19 Q. Okay.</p> <p>20 A. Amongst other things.</p> <p>21 Q. Well, and that's, in essence, been</p> <p>22 your job for many years. Correct?</p> <p>23 A. It's been my job for -- I can go back</p> <p>24 to my CV. I can give you the years that it was my</p> <p>25 job.</p>	<p>1 A. That's what this document describes,</p> <p>2 yes.</p> <p>3 Q. So when it says "all surgeons," that</p> <p>4 doesn't say board certified or not. Right?</p> <p>5 A. That was understood. This document</p> <p>6 wouldn't stand alone.</p> <p>7 Q. What did you do as director of</p> <p>8 professional education to make sure that was</p> <p>9 understood within your company and the sales reps</p> <p>10 that were out there recruiting doctors?</p> <p>11 A. We facilitated training for the sales</p> <p>12 representatives. And, you know, during that time,</p> <p>13 it would be explained to them who the target</p> <p>14 surgeons were for each of the different types of</p> <p>15 products that we provided education for.</p> <p>16 Q. So what training did professional</p> <p>17 education provide for the sales reps?</p> <p>18 A. We provided training during their</p> <p>19 sales school. We provided training during their</p> <p>20 national training meeting. There was individual</p> <p>21 one-off training that professional education</p> <p>22 managers would have provided to sales</p> <p>23 representatives, either over the phone or in person.</p> <p>24 Q. Were there videos created for sales</p> <p>25 reps on prof ed?</p>

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<p>1 A. There were videos created on the</p> <p>2 procedures and sales reps had access to those videos</p> <p>3 on procedures. The videos that prof ed provided</p> <p>4 were those that were intended for surgeon training,</p> <p>5 physician training.</p> <p>6 Q. So at these sales schools and</p> <p>7 national training meetings, how were they trained by</p> <p>8 prof ed? Was it stand up and do a PowerPoint? Was</p> <p>9 it -- what was it?</p> <p>10 A. Yeah. Typically a PowerPoint would</p> <p>11 be one of the ways that it would be done.</p> <p>12 Q. Did you yourself do any of these</p> <p>13 training sessions?</p> <p>14 A. I may have.</p> <p>15 Q. And you would agree that when</p> <p>16 training sales reps about the use of the TVT</p> <p>17 products, that that training also needed to be fair</p> <p>18 and balanced. Correct?</p> <p>19 A. Yes.</p> <p>20 Q. Because if the sales reps received</p> <p>21 information that wasn't fair and balanced, they</p> <p>22 might communicate that to physicians as well in an</p> <p>23 unfair way. Correct?</p> <p>24 A. Yeah. I'd just like to clarify, my</p> <p>25 department wasn't responsible for training sales</p>	<p>1 Q. And then you talked about the</p> <p>2 proctorships. Right?</p> <p>3 A. Yes.</p> <p>4 Q. That's where a physician is in the</p> <p>5 hospital overseeing the operation by one of the</p> <p>6 trainees; is that right?</p> <p>7 A. Yes.</p> <p>8 Q. And that's the "last resort for large</p> <p>9 targets that are unable to learn the procedure</p> <p>10 through other courses." Is that what this says?</p> <p>11 A. That's what this document says, yes.</p> <p>12 Q. This document is TVT SECUR, but the</p> <p>13 same principle would apply to any of the TVT</p> <p>14 products; is that right?</p> <p>15 A. I'd have to see the documents for the</p> <p>16 other TVT products.</p> <p>17 Q. Well, sir, you're the director of</p> <p>18 professional education.</p> <p>19 Do you know as we sit here today</p> <p>20 whether that's true or not?</p> <p>21 A. I don't know.</p> <p>22 Q. And telesurgeries are those that were</p> <p>23 performed over the Internet?</p> <p>24 A. Yes. Or through satellite</p> <p>25 connection.</p>
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<p>1 representatives. My answer before referred to</p> <p>2 training sales representatives specifically on</p> <p>3 professional education.</p> <p>4 Q. But you agree that sales</p> <p>5 representatives need to be trained in a fair and</p> <p>6 balanced way so they can communicate information to</p> <p>7 physicians in a fair and balanced way. Correct?</p> <p>8 A. I would agree with that, but I'm</p> <p>9 not -- I would defer that to sales training as being</p> <p>10 the experts in that area.</p> <p>11 Q. So let's --</p> <p>12 We talked about preceptorships.</p> <p>13 That's a live training of actual cases performed by</p> <p>14 preceptors. Correct?</p> <p>15 A. Yes.</p> <p>16 Q. Cadaver labs, that's "the most</p> <p>17 expensive training available;" is that right?</p> <p>18 A. According to this document for TVT</p> <p>19 SECUR, yes.</p> <p>20 Q. And in those cadaver labs, a</p> <p>21 physician who wanted to learn the procedure could do</p> <p>22 the procedure on a cadaver and understand how to</p> <p>23 perform it; is that right?</p> <p>24 A. They could do the procedure on a</p> <p>25 cadaver and understand how to perform it, correct.</p>	<p>1 Q. And we have speaker events and</p> <p>2 webcasts, we talked about those. Right?</p> <p>3 A. Yes.</p> <p>4 THE WITNESS: I'd like to have a</p> <p>5 bathroom break, if I could. Thank you.</p> <p>6 MR. AYLSTOCK: Go off the record.</p> <p>7 THE VIDEOGRAPHER: The time is now</p> <p>8 12:17. This is the end of Disk Number 2. We're</p> <p>9 going off the record.</p> <p>10 - - -</p> <p>11 (A recess was taken from 12:17 p.m.</p> <p>12 to 12:25 p.m.)</p> <p>13 - - -</p> <p>14 THE VIDEOGRAPHER: The time is now</p> <p>15 12:25. This is the beginning of Disk Number 3. We</p> <p>16 are back on the record.</p> <p>17 BY MR. AYLSTOCK:</p> <p>18 Q. We've -- what's the number of this</p> <p>19 document?</p> <p>20 A. 1056 with a T in front of it.</p> <p>21 Q. We've been going over the types of</p> <p>22 professional education program opportunities in</p> <p>23 Exhibit 1056.</p> <p>24 Are there any others you can think of</p> <p>25 for any of the TVT line of products that aren't on</p>

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<p>1 this list?</p> <p>2 A. No.</p> <p>3 Q. Let me show you Exhibit 1057.</p> <p>4 - - -</p> <p>5 (Deposition Exhibit No. T-1057,</p> <p>6 E-mail chain, top one dated 25 May 2011,</p> <p>7 Bates stamped ETH.MESH.05164815 through</p> <p>8 ETH.MESH.05164820, was marked for</p> <p>9 identification.)</p> <p>10 - - -</p> <p>11 BY MR. AYLSTOCK:</p> <p>12 Q. It's an e-mail from Aaron Kirkemo</p> <p>13 sent to you among others. Do you see that?</p> <p>14 A. I do, yes. Thank you.</p> <p>15 Q. Also to Scott Jones.</p> <p>16 Is he marketing, sales?</p> <p>17 A. I believe at this time frame,</p> <p>18 marketing.</p> <p>19 Q. The date on the e-mail is May 2011;</p> <p>20 is that right?</p> <p>21 A. Yes.</p> <p>22 Q. You were director of professional</p> <p>23 education for the TVT products at this time?</p> <p>24 A. Yes.</p> <p>25 Q. Do you remember receiving this?</p>	<p>1 partners. Right?</p> <p>2 A. Yes.</p> <p>3 Q. What he's talking about is the</p> <p>4 institution of a newsletter to customers. Right?</p> <p>5 A. I'm sorry, could I take a minute to</p> <p>6 read that section?</p> <p>7 Q. Okay.</p> <p>8 A. Can you -- I'm sorry, I just after</p> <p>9 reading it didn't remember your question.</p> <p>10 Q. Well, do you recall a time when the</p> <p>11 marketing department engaged medical affairs, prof</p> <p>12 ed, along with some marketing communications about</p> <p>13 the institution of a quarterly newsletter from</p> <p>14 J&J/Ethicon?</p> <p>15 A. It would appear that way from this</p> <p>16 e-mail, yes.</p> <p>17 Q. And this newsletter is called "Female</p> <p>18 Pelvic Medicine & Reconstructive Surgery."</p> <p>19 Do you see that?</p> <p>20 A. I do see that, yes. And this is a</p> <p>21 draft of a newsletter.</p> <p>22 Q. That wasn't copy approved yet.</p> <p>23 Right?</p> <p>24 A. That's what it says here, yes.</p> <p>25 Q. Now, any such newsletter that would</p>
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<p>1 A. I don't remember receiving this, but</p> <p>2 my name was on the distribution, so I probably did.</p> <p>3 Q. Who is Jennifer Paradise?</p> <p>4 A. Jennifer Paradise is a person who</p> <p>5 worked in professional education, I think, at the</p> <p>6 time that this was written. Yes.</p> <p>7 Q. If we turn back to the first e-mail</p> <p>8 on the chain, Brian Luscombe, who is he?</p> <p>9 A. I believe at this point in time,</p> <p>10 Brian Luscombe has been with the company for a</p> <p>11 number of years, but I believe at this point in time</p> <p>12 he was in marketing.</p> <p>13 Q. So Brian e-mails from the marketing</p> <p>14 department to Piet Hinoul, Aaron Kirkemo in medical</p> <p>15 affairs. Right?</p> <p>16 A. I'm sorry, are you on the first</p> <p>17 page or --</p> <p>18 Q. The very first e-mail on the chain</p> <p>19 from May 12th at 1:24 p.m.</p> <p>20 A. Yes.</p> <p>21 Q. Then you're listed along with</p> <p>22 Ms. Paradise and then some others?</p> <p>23 A. Yes.</p> <p>24 Q. And he's addressing it to medical</p> <p>25 affairs, prof ed and marketing communications</p>	<p>1 go out from J&J/Ethicon would need to be copy</p> <p>2 approved. Right?</p> <p>3 A. Yes, it would.</p> <p>4 Q. By marketing. Right? Would they --</p> <p>5 A. By the copy review board, the</p> <p>6 cross-functional team that we spoke about before.</p> <p>7 Q. That would include marketing. Right?</p> <p>8 A. Marketing was not part of the copy</p> <p>9 review approval.</p> <p>10 Q. For what? For anything?</p> <p>11 A. I don't think so, no.</p> <p>12 Q. Because I think you testified earlier</p> <p>13 today that they were. Do you know?</p> <p>14 A. I don't know for sure. I would defer</p> <p>15 that to the marketing services department.</p> <p>16 Q. Prof ed would need to copy approve</p> <p>17 it. Right?</p> <p>18 A. Prof ed would need to copy approve</p> <p>19 it, yes.</p> <p>20 Q. As this --</p> <p>21 A quarterly newsletter to doctors</p> <p>22 would be part of prof ed. Right?</p> <p>23 A. This was something, from my</p> <p>24 understanding of this e-mail, that Mr. Luscombe was</p> <p>25 proposing. What's attached here is a draft. I</p>

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<p>1 don't recall that this newsletter ever came to 2 fruition, so this was a concept that seems from this 3 e-mail that Mr. Luscombe is suggesting. 4 Q. Is it your understanding that it was 5 never sent or you just have no idea? 6 A. I don't have knowledge that this 7 newsletter was sent. 8 Q. Do you know that it -- 9 Do you know one way or the other? 10 A. I don't know. I would address that 11 to Mr. Luscombe. 12 Q. Well, the idea of this -- 13 You would agree, though, that if it 14 was sent, it would be part of professional 15 education's responsibility to make sure that it was 16 accurate. Correct? 17 A. I think he's consulting professional 18 education to get our input on this concept. 19 Q. And the idea of this newsletter is to 20 penetrate teaching institutions throughout the 21 United States. That's what he says. Right? 22 A. It does say that, yes. 23 Q. You would agree that if it was 24 sent -- well, I'll strike that. 25 He's also talking about -- if we go</p>	<p>1 and was issued as a newsletter. But as I sit here 2 today, I can't recall that that occurred. 3 Q. Do you know of any newsletters that 4 were ever instituted for any of the pelvic floor 5 products of J&J along these lines? 6 A. I believe there were some newsletters 7 in the history of the pelvic floor and TVT products. 8 Q. Tell me what you recall about those. 9 A. I can recall probably around 2002 or 10 2003 some newsletters being issued to some of the 11 doctors that taught professional education for us. 12 Q. Okay. 13 And those would have been part of 14 professional education. Correct? 15 A. Those would have been part of -- 16 professional education would have been involved in 17 that, yes. 18 Q. And they would have needed to have 19 been copy reviewed. Correct? 20 A. Yes. 21 Q. And they would have needed to be 22 accurate and fair and balanced. Correct? 23 A. Yes, yes. 24 Q. And they would have needed to 25 communicate any risk information in a fair and</p>
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<p>1 to Jennifer Paradise, the second page of the e-mail. 2 She's in prof ed; is that right? 3 A. At this time, yes. 4 Q. And she really likes the idea and the 5 format. Right? 6 A. That's what she's saying in this 7 e-mail, yes. 8 Q. Was she your -- under your management 9 at that time? 10 A. Yes. 11 Q. Okay. 12 And then Aaron Kirkemo weighs in. 13 He's director of medical affairs; is 14 that right? 15 A. Yes. 16 Q. And he agrees and thinks it looks 17 good. Right? 18 A. Yes. 19 Q. And you have no knowledge about 20 whether this was implemented or not? 21 A. I don't. From this communication, it 22 looks like this was a concept that Brian was looking 23 to get input from various people, and they provided 24 their input to Mr. Luscombe. I would defer to him 25 as to whether this did proceed to go to copy review</p>	<p>1 balanced way. Correct? 2 A. Yes. 3 Q. Do you recall ever signing off on any 4 of those? 5 A. I don't recall signing off on this. 6 Q. Did you ever sign off on -- did you 7 personally ever sign off on any copy-reviewed prof 8 ed items? 9 A. No. 10 Q. Who would have done that in your 11 department? 12 A. The copy review board would have 13 signed off on the use of documents that went through 14 copy review. 15 Q. So we talked about all the items on 16 the list, Exhibit 156. And then we talked about 17 some medical education newsletters that were sent 18 out. 19 Any other types of professional 20 education that you know about? 21 A. No. And just to clarify, from my 22 knowledge and memory, this newsletter was not sent 23 out. But you're talking in general. 24 Q. There were other newsletters that 25 were sent out?</p>

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<p>1 A. Yes, my apologies. There was a 2 newsletter that I do recall at one point over the 3 years that these products were made available by the 4 company. 5 Q. Was it stopped at some point in time? 6 A. I don't think it was stopped at any 7 point in time. It was -- 8 Q. So it's still going? 9 A. I don't think it was intended to be 10 an ongoing thing. There might have been a need to 11 or desire to communicate some information, and that 12 information was made available in the form of a 13 newsletter. 14 Q. Now, other types of professional 15 education would include the IFU? 16 A. No. The IFU is not professional 17 education. It's not a professional education-owned 18 document. Regulatory affairs owns the IFU. 19 Q. Does regulatory affairs own the 20 patient brochure as well? 21 A. No. Regulatory affairs doesn't own 22 the patient brochure. 23 Q. That would be marketing, sales? 24 A. Marketing. 25 Q. Marketing owns the patient brochure.</p>	<p>1 A. She was my boss. 2 Q. In professional education? 3 A. Yes. 4 Q. Let me show you Exhibit 1058. 5 - - - 6 (Deposition Exhibit No. T-1058, 7 E-mail chain, top one dated 06 Sep 2003, 8 Bates stamped ETH.MESH.03738468 through 9 ETH.MESH.03738470, was marked for 10 identification.) 11 - - - 12 BY MR. AYLSTOCK: 13 Q. I direct your attention to the e-mail 14 from Marianne Kaminski to Zenobia Walji, the first 15 one in the chain, September 5, 2003. Do you see 16 that? 17 A. Yes, I do. 18 Q. And the subject is "TVT Response for 19 Peggy Norton, M.D." do you see that? 20 A. I do, yes. 21 Q. And apparently what Peggy Norton, 22 Dr. Norton asked is, "Is there precedent for 23 industry being responsible for making certain that 24 surgeons are approved" and "certified to use new 25 devices" and "equipment?" Do you see that question?</p>
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<p>1 When it comes to training physicians 2 on the safe use of the product, you would agree that 3 Ethicon/J&J had a duty to properly train those 4 doctors. Right? 5 MR. BROWN: Objection. 6 THE WITNESS: Ethicon did its best to 7 properly train the doctors on the use of our 8 products. 9 BY MR. AYLSTOCK: 10 Q. Well, based upon the credo that we 11 just went under, you would agree that they had a 12 duty to do that, to provide adequate training on the 13 products, how to be safely and effectively used in 14 the right patient population. Correct? 15 MR. BROWN: Objection. 16 THE WITNESS: I can't speak on behalf 17 of Ethicon. My personal involvement in professional 18 education was to provide training by surgeons to 19 surgeons on the use of our product. 20 BY MR. AYLSTOCK: 21 Q. Who was Marianne Kaminski? 22 A. Marianne Kaminski worked in 23 professional education up until I think 24 approximately 2005, the end of 2005. 25 Q. Was she your boss at one time?</p>	<p>1 A. Yes. 2 Q. And Marianne Kaminski answers that. 3 Do you see that? 4 A. I see that, yes. 5 Q. And what does she say, as director of 6 professional education at the time? 7 A. Could I have a moment to read it? 8 Q. Sure. 9 A. Thank you. 10 Q. Do you see where she says, "I can't 11 answer...for the whole industry, but there is a 12 precedent for Johnson & Johnson to be responsible 13 when introducing new technology, based on our 14 CREDO." Do you see that? 15 A. I do, yes. 16 Q. And then she says, "Simply put, it is 17 the right thing for us to do so that we can be a 18 partner for life for all constituents (Physicians, 19 Patients, Payers, Sites of care)." Do you see that? 20 A. I do see that, yes. 21 Q. And you agree with that. Right? 22 It's the right thing to do to offer training so that 23 the correct patients will receive the product and 24 they'll be received in the safest manner possible. 25 Correct?</p>

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<p>1 A. Can you rephrase that as a single 2 question, please? 3 MR. BROWN: Just -- 4 BY MR. AYLSTOCK: 5 Q. Well, do you agree that it's the 6 right thing to do that Johnson -- 7 Well, do you agree that the correct 8 thing, consistent with the credo, when Johnson & 9 Johnson is going to introduce a new technology like 10 the TVT products, to provide training for that 11 product and to make sure that only responsible 12 surgeons that are approved and certified should use 13 the device? 14 A. Yes. 15 Q. Now, what does Ethicon do to ensure 16 that only properly trained physicians use the TVT 17 products? 18 A. I'm not sure that I can answer that 19 question outside of professional education. 20 Q. No. I'm asking you as the former 21 director of professional education, training 22 physicians, what is done to ensure that only 23 properly trained physicians are putting in your 24 company's products? 25 MR. BROWN: Objection.</p>	<p>1 Q. On the third page, it has you as the 2 director of professional education. Right? 3 A. That's correct. 4 Q. And then under you are some of these 5 regional managers. Right? 6 A. Yes. 7 Q. And then the next page has -- 8 A. Just to correct. It's prof ed 9 development manager is the title of the people that 10 reported to me. 11 Q. Which, in essence, is -- they're 12 divided by regions of the country. Right? 13 A. They are divided by regions of the 14 country. Correct. 15 Q. Now, if we look at page 6, "Prof Ed 16 Programs," do you see that? 17 A. Yes. 18 Q. We have the preceptorships, the 19 proctorships, the telesurgeries and the cadaver labs 20 and the PCP awareness programs. Do you see that? 21 A. Yes, I do. 22 Q. Is that newsletter we were talking 23 about an example of a PCP awareness program? 24 A. No. 25 Q. What's a PCP awareness program then?</p>
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<p>1 THE WITNESS: There's a selection 2 criteria for physicians that's communicated. 3 There's a system of checks and balances that 4 surgeons that attend training meet our selection 5 criteria. And once those surgeons attend training, 6 they come into a list that -- of surgeons that 7 attended training and the company will provide 8 product to. 9 BY MR. AYLSTOCK: 10 Q. Let me show you Exhibit 1059. 11 - - - 12 (Deposition Exhibit No. T-1059, 13 PowerPoint, "Ethicon Women's Health & 14 Urology," Bates stamped ETH.MESH.00235558 15 through ETH.MESH.00235570, was marked for 16 identification.) 17 - - - 18 BY MR. AYLSTOCK: 19 Q. You've seen this PowerPoint before, 20 haven't you? 21 A. I have, yes. 22 Q. In fact, this is your PowerPoint. 23 Right? 24 A. I believe so. From it looks like 25 around 2006.</p>	<p>1 A. A PCP awareness program would be a 2 surgeon that performs the -- one of the procedures 3 providing education to physicians in their 4 community, primary care physicians in their 5 community, about the disease state of incontinence, 6 treatment options that were available. 7 Q. So these are materials you provide to 8 surgeons that use your product to drive business, 9 drive people to ask for your product. Right? 10 A. No, I wouldn't say it that way. 11 These are materials that we provided to physicians 12 that use the product to educate other physicians 13 that work with them in their community about the 14 disease state of incontinence and treatment options. 15 Q. And you did that so that your company 16 could sell more product. Right? 17 A. That might have been one outcome, 18 but the -- one intent -- the primary intent was to 19 educate primary care physicians on the disease state 20 of incontinence and treatment options that were 21 available. 22 Q. Well, you're not training primary 23 care physicians how to do this surgery. Right? 24 A. No. 25 Q. So you're --</p>

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<p>1 The reason that you're trying to</p> <p>2 raise awareness is so that they will refer cases to</p> <p>3 physicians that do your surgery. Correct?</p> <p>4 A. No. The content that was used for</p> <p>5 these programs discussed all different treatment</p> <p>6 options, including nonsurgical treatment options.</p> <p>7 Q. You also had a program where you</p> <p>8 would provide web content for physicians on the use</p> <p>9 of the TVT product for their patients. Correct?</p> <p>10 A. That wasn't part of the professional</p> <p>11 education, so I have no direct knowledge of that.</p> <p>12 Q. But you know that happened. Right?</p> <p>13 You know that was part of what your company did.</p> <p>14 Correct?</p> <p>15 A. I'm aware that that was something</p> <p>16 that another function of the company did, and I</p> <p>17 would defer to that.</p> <p>18 Q. That would have been part of the</p> <p>19 marketing function?</p> <p>20 A. I believe so, yes.</p> <p>21 Q. You have a budget there, cost per</p> <p>22 doctor, a couple pages in for the TVT and TVT-O</p> <p>23 along with the Prolift?</p> <p>24 A. Yes.</p> <p>25 Q. And then you're tracking sales per</p>	<p>1 Q. And "Target key accounts" and</p> <p>2 "physicians." Right?</p> <p>3 A. Yes.</p> <p>4 Q. And on the next page, "Do's and</p> <p>5 Don'ts," you're telling the physician -- the sales</p> <p>6 reps to "use professional education as a tool."</p> <p>7 Right?</p> <p>8 A. Yes.</p> <p>9 Q. A tool to sell the product. Correct?</p> <p>10 A. A tool to train doctors on the safe</p> <p>11 and effective use of the product.</p> <p>12 MR. AYLSTOCK: Move to strike.</p> <p>13 BY MR. AYLSTOCK:</p> <p>14 Q. This is a presentation to sales reps.</p> <p>15 Right?</p> <p>16 A. This is a presentation to sales reps,</p> <p>17 correct.</p> <p>18 Q. And sales reps are there to sell the</p> <p>19 product. Right?</p> <p>20 A. I think that's one of their</p> <p>21 responsibilities. They're also representatives of</p> <p>22 the product to doctors in their territory.</p> <p>23 MR. AYLSTOCK: Move to strike after</p> <p>24 "responsibilities."</p> <p>25 BY MR. AYLSTOCK:</p>
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<p>1 doctor and costs per doctor for those products on</p> <p>2 the next page?</p> <p>3 A. Yes.</p> <p>4 Q. And then you're -- on the next page</p> <p>5 you're looking at return on investment. Right?</p> <p>6 A. Yes.</p> <p>7 Q. So you have the number of doctors</p> <p>8 trained, the number of units sold and the units for</p> <p>9 doctor trained all broken out?</p> <p>10 A. Yes.</p> <p>11 Q. "How Can You Optimize Your Prof Ed</p> <p>12 Dollars?" Do you see that?</p> <p>13 A. Yes.</p> <p>14 Q. Who was this presentation given to</p> <p>15 when you gave it?</p> <p>16 A. I believe this was given to the sales</p> <p>17 department or sales representatives.</p> <p>18 Q. So --</p> <p>19 And you personally gave this</p> <p>20 presentation. Right?</p> <p>21 A. I believe so, yes.</p> <p>22 Q. So on the next page, you're telling</p> <p>23 the sales reps to "Build Professional Education into</p> <p>24 your business plan." Right?</p> <p>25 A. Yes.</p>	<p>1 Q. Sales reps aren't a part of</p> <p>2 professional education or they are a part of</p> <p>3 professional education?</p> <p>4 A. They are not part of professional</p> <p>5 education.</p> <p>6 Q. So you're telling these sales reps to</p> <p>7 use professional education as a tool for them in</p> <p>8 their sales. Correct?</p> <p>9 A. As a tool in their jobs.</p> <p>10 Q. Their job is to sell a product. It's</p> <p>11 not surprising. Right?</p> <p>12 A. It's amongst their jobs, yes.</p> <p>13 Q. And then on the last page, you have</p> <p>14 TVT-O adoption rates. Do you see that?</p> <p>15 A. Yes.</p> <p>16 Q. So you know how many surgeons went to</p> <p>17 the telesurgery, how many went to the proctorship,</p> <p>18 how many went to the preceptorship, how many went to</p> <p>19 the cadaver. Right?</p> <p>20 A. Yes.</p> <p>21 Q. You track that, you know what</p> <p>22 surgeons went to what program. Correct?</p> <p>23 A. That's correct.</p> <p>24 Q. And how is that tracked within</p> <p>25 professional education?</p>

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<p>1 A. There's a -- documents and a 2 registration system that's used in professional 3 education. 4 Q. What's the name of that system? 5 A. Professional education registration 6 system. 7 Q. It's a database or a computer program 8 or what? 9 A. It's a computer program, yes. 10 Q. So whenever a doctor signs up for 11 telesurgery, you know on what date that doctor 12 attended. Correct? 13 A. I -- yes. 14 Q. You know what hospital that doctor is 15 associated with. Right? 16 A. Yes. 17 Q. And you know what presentation was 18 made to that doctor at that telesurgery. You keep 19 track of that. Right? 20 A. I believe so, yes. 21 Q. So if I have a physician who 22 implanted a TVT product in one of my clients, your 23 company should be able to tell me when that 24 physician went for training, whether they went for 25 training and what presentation they viewed.</p>	<p>1 marketing signs off on prof ed copy review? 2 A. Yes. 3 Q. And they do, don't they? 4 A. They do, yes. 5 Q. And the other had to do with the 6 materials provided to doctors at individual training 7 sessions? 8 A. That's correct. 9 Q. And so your company knows which 10 training sessions were performed -- were attended by 11 every single doctor. Right? They keep track of 12 that? 13 A. Yes. 14 Q. And they keep track of what -- the 15 dates of that and what was copy reviewed at that 16 time? 17 A. Yes. 18 Q. And is there something else you 19 wanted to correct? 20 A. I believe you asked me if 21 professional education was one of the approvers in 22 copy review, and I would like to clarify that 23 professional education is not one of the approvers 24 in copy review. 25 Q. For any of the -- even the prof ed</p>
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<p>1 Correct? 2 A. Yes. 3 MR. AYLSTOCK: Let's break for lunch. 4 THE VIDEOGRAPHER: The time is now 5 12:51. We're going off the record. 6 - - - 7 (A luncheon recess was taken from 8 12:51 p.m. to 1:39 p.m.) 9 - - - 10 (Deposition Exhibit No. T-1060, 11 E-mail chain, top one dated February 08, 12 2011, Bates stamped ETH.MESH.05570260 and 13 ETH.MESH.05570261, was marked for 14 identification.) 15 - - - 16 THE VIDEOGRAPHER: The time is now 17 1:39. We are back on the record. 18 BY MR. AYLSTOCK: 19 Q. Mr. Parisi, we are back after lunch 20 and I have a document that you've had a chance to 21 review, but I understand that you provided some 22 testimony before lunch that now you want to correct; 23 is that right? 24 A. That's correct. 25 Q. One item had to do with whether</p>	<p>1 slide decks? 2 A. The prof ed slide decks, they would 3 be involved in that cross-functional team, but as 4 far as the copy review committee, I want to be very 5 specific that the copy review committee includes the 6 functions that I had mentioned before, but it 7 doesn't include professional education as an 8 approver. 9 Q. So let me get this straight. 10 For the professional education 11 materials, they have to be approved by marketing, 12 the copy review team includes marketing? 13 A. Yes. 14 Q. Includes medical? 15 A. Yes. 16 Q. Includes sales? 17 A. No. 18 Q. It includes regulatory? 19 A. Yes. 20 Q. And legal? 21 A. Yes. 22 Q. But not professional ed? 23 A. They're not on the copy review board; 24 however, they would be involved in the team that 25 prepared the materials that was submitted for copy</p>

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<p>1 review. So they're involved in the process.</p> <p>2 Q. But they don't have to sign off on</p> <p>3 whether this is consistent with their principles in</p> <p>4 professional education?</p> <p>5 A. Just to clarify, they're not on the</p> <p>6 copy review board, so there are records of who was</p> <p>7 on the board when a particular document was</p> <p>8 approved. And in my recollection as I sit here</p> <p>9 today, I don't recall professional education being</p> <p>10 listed among those approvers.</p> <p>11 Q. Exhibit 1060 in front of you, do you</p> <p>12 see that?</p> <p>13 A. Yes.</p> <p>14 Q. February 8, 2011?</p> <p>15 A. Yes.</p> <p>16 Q. You're sending an e-mail regarding an</p> <p>17 FDA request for a copy of all surgical training</p> <p>18 videos related to pelvic floor repair and SUI</p> <p>19 products?</p> <p>20 A. I believe I'm responding to an e-mail</p> <p>21 that was sent initially from Brian Kanerviko</p> <p>22 forwarded to Alyson Wess. And then I'm responding</p> <p>23 to Alyson Wess's e-mail.</p> <p>24 Q. And it's also Lissette Caro-Rosado?</p> <p>25 A. Yes.</p>	<p>1 education, when you want to go see, I'd like to see</p> <p>2 the TVT-S training video or what have you, how do</p> <p>3 you do that?</p> <p>4 A. It would usually be in electronic</p> <p>5 format, unless it was older, before electronic</p> <p>6 records were keep -- were --</p> <p>7 Q. Start with the electronic.</p> <p>8 What do you do to access it?</p> <p>9 A. The electronic records are kept on an</p> <p>10 internal website.</p> <p>11 Q. Is that called the GGM Blue system?</p> <p>12 A. GGM Blue is one of the systems.</p> <p>13 Q. What does that stand for?</p> <p>14 A. Global graphics management system, I</p> <p>15 believe, but I would defer that to somebody in</p> <p>16 that -- the department that runs that system.</p> <p>17 Q. And then as far as a surgical</p> <p>18 training video that was in use previously, how would</p> <p>19 you go about finding those?</p> <p>20 A. There would be copies of the actual</p> <p>21 video kept in archive with the copy review</p> <p>22 department.</p> <p>23 Q. And so were you able to answer this</p> <p>24 request from the FDA and provide the surgical</p> <p>25 training videos that they requested?</p>
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<p>1 Q. Did she take your position as</p> <p>2 worldwide director of professional education when</p> <p>3 you went to Ethicon Biosurgery?</p> <p>4 A. Yes.</p> <p>5 Q. Is she still in Ethicon professional</p> <p>6 education?</p> <p>7 A. No.</p> <p>8 Q. Where she's at?</p> <p>9 A. To my knowledge, she's no longer with</p> <p>10 Ethicon.</p> <p>11 Q. Do you know where she went?</p> <p>12 A. I don't.</p> <p>13 Q. Do you know when she went?</p> <p>14 A. It was probably about a year ago.</p> <p>15 Q. Do you know why she left?</p> <p>16 A. She was displaced during the</p> <p>17 restructuring. To the best of my knowledge, her</p> <p>18 position was eliminated.</p> <p>19 Q. So the FDA is requesting copies of</p> <p>20 all the surgical training videos for all the TVT</p> <p>21 products, among others. Right?</p> <p>22 A. Yes.</p> <p>23 Q. Where are those housed within</p> <p>24 Ethicon? Is there a file cabinet or an electronic</p> <p>25 database or -- as director of professional</p>	<p>1 A. Yes, I believe so.</p> <p>2 Q. Did you provide them all of the</p> <p>3 surgical training videos historically or only those</p> <p>4 that were in use at the time?</p> <p>5 A. I can't recall as I sit here today,</p> <p>6 but we tried to understand the requests that they</p> <p>7 were making and conform with that to the</p> <p>8 satisfaction of the regulatory affairs department,</p> <p>9 who was the requester of this.</p> <p>10 Q. Who is Nancy Leclair?</p> <p>11 A. Nancy Leclair was in charge of</p> <p>12 marketing services.</p> <p>13 Q. And do you recall whether she handled</p> <p>14 this for the FDA?</p> <p>15 A. I don't recall.</p> <p>16 Q. So Ethicon can tell the FDA and</p> <p>17 anybody who asks what surgical training videos are</p> <p>18 in effect at a certain period of time; is that</p> <p>19 correct?</p> <p>20 A. Yes.</p> <p>21 Q. And historically, is it your</p> <p>22 understanding that they keep records of what</p> <p>23 surgical training videos were in effect at certain</p> <p>24 periods of time?</p> <p>25 A. Yes.</p>

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<p>1 Q. And do you keep track of the in-use</p> <p>2 dates for those surgical training videos?</p> <p>3 A. I believe the marketing services</p> <p>4 department keeps track of those.</p> <p>5 Q. It's important if a surgical training</p> <p>6 video is updated for some reason that the old</p> <p>7 training video gets pulled from the sources in</p> <p>8 professional education so stale information doesn't</p> <p>9 get provided to physicians. Right?</p> <p>10 A. That would be our intent.</p> <p>11 Q. So it's your understanding that you</p> <p>12 can provide in-use dates for each training video so</p> <p>13 that you know when a video kind of came offline and</p> <p>14 when a new one came on?</p> <p>15 A. I believe so, but I would defer that</p> <p>16 to the marketing services department that owns that</p> <p>17 process.</p> <p>18 Q. Who in marketing services? Would</p> <p>19 that be Nancy Leclair?</p> <p>20 A. Currently it would be Eric Dunn, I</p> <p>21 believe.</p> <p>22 Q. Let me mark for you Exhibit 1061.</p> <p>23 - - -</p> <p>24 (Deposition Exhibit No. T-1061,</p> <p>25 TVT/SUI Professional Education Index and</p>	<p>1 MR. AYLSTOCK: -- at 10:00 p.m.</p> <p>2 before this deposition began.</p> <p>3 MR. BROWN: Right, yes. So that was</p> <p>4 prepared by counsel, so you can either -- and not</p> <p>5 by Martin.</p> <p>6 THE WITNESS: Oh, my apologies. I</p> <p>7 don't know the origin of this document. I can</p> <p>8 clarify that I have seen this document before. And</p> <p>9 it's my understanding that this was prepared by</p> <p>10 counsel.</p> <p>11 BY MR. AYLSTOCK:</p> <p>12 Q. Did you see it in preparation for</p> <p>13 your deposition?</p> <p>14 A. I see that it's in preparation for</p> <p>15 the Pelvic Mesh/Gynecare litigation.</p> <p>16 Q. How recently have you seen the</p> <p>17 document or how -- when did you see it, do you</p> <p>18 recall? A week ago, a month ago, last night?</p> <p>19 A. I would say it was probably within</p> <p>20 the last week or so. I can't recall as I sit here</p> <p>21 today.</p> <p>22 MR. BROWN: I'm going to represent to</p> <p>23 you that we have not provided that document to Paul,</p> <p>24 so he is not -- he's not seen it in -- I mean, I</p> <p>25 have not provided that document to you.</p>
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<p>1 Production Bates Range Chart, 4 pages, was</p> <p>2 marked for identification.)</p> <p>3 - - -</p> <p>4 BY MR. AYLSTOCK:</p> <p>5 Q. Have you ever seen that chart before?</p> <p>6 A. Yes, I think I've seen this.</p> <p>7 Q. Were you involved in the preparation</p> <p>8 of the document?</p> <p>9 A. The document, I think, was prepared</p> <p>10 by the marketing services department, but I do</p> <p>11 recall seeing it.</p> <p>12 Q. And is that an accurate</p> <p>13 representation of the surgical training videos and</p> <p>14 other professional education materials for the TVT</p> <p>15 products, to the best of your understanding?</p> <p>16 A. Yes.</p> <p>17 MR. BROWN: I'm just going to put on</p> <p>18 the record that all of you might want to -- you</p> <p>19 know, Bryan, you can decide how you want to handle</p> <p>20 this. That's a document that's prepared by counsel.</p> <p>21 This is what we've provided to you, you didn't give</p> <p>22 me another copy, so just to --</p> <p>23 MR. AYLSTOCK: That was provided to</p> <p>24 me by Mr. Watson --</p> <p>25 MR. BROWN: Yes.</p>	<p>1 THE WITNESS: Yeah. No, that counsel</p> <p>2 did not provide it to me, so this -- if I have seen</p> <p>3 it before, I mean, I see a lot of spreadsheets, it's</p> <p>4 very difficult for me to say, you know, looking at</p> <p>5 this if this was the exact same spreadsheet that</p> <p>6 I've seen in the past.</p> <p>7 BY MR. AYLSTOCK:</p> <p>8 Q. Your company has spreadsheets of the</p> <p>9 in-use dates for the training materials on the TVT</p> <p>10 products. You've seen those. Right?</p> <p>11 A. That's my understanding.</p> <p>12 Q. And where would those be kept? Do</p> <p>13 you have a file of them? Are they in your e-mail</p> <p>14 system or where would you have seen those?</p> <p>15 A. I believe that they would be in the</p> <p>16 GGM Blue system that we had spoken of before.</p> <p>17 Q. Okay.</p> <p>18 A. Or in -- archived in the copy review</p> <p>19 department.</p> <p>20 - - -</p> <p>21 (Deposition Exhibit No. T-1062, TVT</p> <p>22 Professional Education Program, Bates</p> <p>23 stamped ETH.MESH.00156909 through</p> <p>24 ETH.MESH.00156938, was marked for</p> <p>25 identification.)</p>

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<p>1 - - -</p> <p>2 BY MR. AYLSTOCK:</p> <p>3 Q. Let me show you Exhibit T-1062, which</p> <p>4 is a TVT Professional Education Program. It's one</p> <p>5 of the documents that was listed on the grid. I</p> <p>6 think it was number 2 on the grid.</p> <p>7 Do you recognize this as a type of</p> <p>8 professional education used by Ethicon for the TVT?</p> <p>9 A. Yes.</p> <p>10 Q. And how would you describe this</p> <p>11 document to the jury? Is this a slide deck or what</p> <p>12 is it exactly? How is it used by your company?</p> <p>13 A. This was used in 1998 for</p> <p>14 professional education. I wasn't in the</p> <p>15 professional education department in 1998. It would</p> <p>16 appear to be something that would be used within the</p> <p>17 professional education programs discussing different</p> <p>18 aspects of the TVT procedure.</p> <p>19 Q. Turn with me to 928.</p> <p>20 You see the writing there at the top?</p> <p>21 A. Yes.</p> <p>22 Q. Would you agree with me that this is</p> <p>23 not a final version of the TVT professional</p> <p>24 education program?</p> <p>25 A. I don't -- well, I don't know. This</p>	<p>1 A. My job is to facilitate the transfer</p> <p>2 of information. I was not personally involved in</p> <p>3 teaching, as that was the role of our surgeon</p> <p>4 faculty or preceptors.</p> <p>5 Q. Well, in doing your job, you had to</p> <p>6 have some understanding about the medical principles</p> <p>7 involved in the pelvic floor anatomy. Correct?</p> <p>8 A. I had to have layperson's knowledge,</p> <p>9 but I was not the person that would be doing the</p> <p>10 teaching. We left that up to surgeons who were</p> <p>11 qualified to teach other surgeons.</p> <p>12 Q. Even when you were -- back in 2001</p> <p>13 when you were a sales rep for Ethicon/J&J, you had</p> <p>14 to have some basic understanding of those medical</p> <p>15 principles when you were interacting with doctors</p> <p>16 selling products. Right?</p> <p>17 A. In 2001 I was a sales representative</p> <p>18 for a different division of Johnson & Johnson. I</p> <p>19 had no involvement with the TVT products.</p> <p>20 Q. No.</p> <p>21 But you were selling medical products</p> <p>22 at that time. Right?</p> <p>23 A. Yes.</p> <p>24 Q. And you know as a sales rep that one</p> <p>25 of the things your company does is make sure the</p>
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<p>1 is from 1998. I can't say that I have any</p> <p>2 recollection of what the -- what this note might</p> <p>3 have meant.</p> <p>4 Q. When you became director of</p> <p>5 professional education, did you undertake to review</p> <p>6 all of the current -- the materials that were in</p> <p>7 effect at the time you became director?</p> <p>8 A. Yes. When I started that job at the</p> <p>9 end of 2005, I made every effort to be knowledgeable</p> <p>10 about the materials that were current and currently</p> <p>11 used within the department.</p> <p>12 Q. So you reviewed all of the videos</p> <p>13 that were in effect?</p> <p>14 A. Yes.</p> <p>15 Q. You reviewed all the handouts and</p> <p>16 other professional education slide decks?</p> <p>17 A. Yes.</p> <p>18 Q. Did you undertake any training on</p> <p>19 medical principles involved in pelvic floor anatomy?</p> <p>20 A. Yes. I probably had some training to</p> <p>21 that effect.</p> <p>22 Q. Because your job is to help</p> <p>23 communicate information to physicians and facilitate</p> <p>24 the transfer of that information as director of</p> <p>25 professional education. Right?</p>	<p>1 sales reps have an understanding of not only the</p> <p>2 product but how the product is used so they can talk</p> <p>3 to a doctor and sell the product. Correct?</p> <p>4 A. Yes.</p> <p>5 Q. And when it comes to your role as</p> <p>6 director of professional education, you became</p> <p>7 familiar with some of the definitions of the medical</p> <p>8 terms involved in the pelvic floor anatomy?</p> <p>9 A. Yes.</p> <p>10 Q. You attended medical conventions and</p> <p>11 talked to doctors at those conventions?</p> <p>12 A. Yes.</p> <p>13 Q. And you did that as product director,</p> <p>14 too, didn't you?</p> <p>15 A. I did, yes.</p> <p>16 Q. In fact, you went to the American</p> <p>17 Urogynecological Society annual meeting and handed</p> <p>18 out materials during that, didn't you?</p> <p>19 A. I may have. I do -- I can say that I</p> <p>20 definitely attended the American Urogynecologic</p> <p>21 Society meeting. Maybe not annually.</p> <p>22 Q. And the reason that you did that was,</p> <p>23 in part, to help you learn about the pelvic floor</p> <p>24 anatomy and how these products are used so that you</p> <p>25 could do your job as director of professional</p>

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<p>1 education or product director, whatever it was at</p> <p>2 the time. Right?</p> <p>3 A. Yes, in part.</p> <p>4 Q. Now, when you were a sales rep for</p> <p>5 Ethicon, were you told to train doctors on how to</p> <p>6 use the product?</p> <p>7 A. No.</p> <p>8 Q. In fact, you were told not to train</p> <p>9 doctors. Correct? You were told to leave that to</p> <p>10 professional education. Right?</p> <p>11 A. Yes, that's my understanding.</p> <p>12 Q. And the reason is because sales</p> <p>13 representatives aren't physicians, and they can't</p> <p>14 practice medicine or they shouldn't be practicing</p> <p>15 medicine. Right?</p> <p>16 A. That's correct.</p> <p>17 Q. So you understood that one of the</p> <p>18 principles for any sales rep is your job is not to</p> <p>19 train doctors on how to practice medicine and</p> <p>20 perform the procedure, their job is to mainly sell</p> <p>21 the product. Right?</p> <p>22 MR. BROWN: Objection.</p> <p>23 THE WITNESS: As I explained before,</p> <p>24 the job of the sales representative is to represent</p> <p>25 the products that they sell. In representing the</p>	<p>1 whether -- how the procedure should be done and the</p> <p>2 doctor had a question about the preceptor's training</p> <p>3 and directed it to the sales rep, you would agree</p> <p>4 that the sales rep should direct the doctor or the</p> <p>5 preceptor to clarify any misunderstandings or</p> <p>6 ambiguity in the training. Correct?</p> <p>7 A. Yes.</p> <p>8 Q. It wouldn't be appropriate for the</p> <p>9 sales rep to communicate what the preceptor meant</p> <p>10 and clarify something for the doctor. Correct?</p> <p>11 A. If it was in the IFU, I think it</p> <p>12 would be appropriate for the sales rep to show the</p> <p>13 doctor the IFU and help them -- they're a resource</p> <p>14 to the doctor that they work with to help them have</p> <p>15 the information they need to utilize our products.</p> <p>16 Q. And if that information wasn't in the</p> <p>17 IFU, it's not up to the sales rep to clarify what</p> <p>18 the preceptor meant during training. You would</p> <p>19 agree with that?</p> <p>20 A. I would say that the IFU is not the</p> <p>21 only education document but comprehensive of all</p> <p>22 education documents that were provided to the</p> <p>23 doctor, the sales rep could certainly provide</p> <p>24 clarity as long as it was consistent with the</p> <p>25 documents that were provided through professional</p>
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<p>1 products, they'd also have to be knowledgeable of</p> <p>2 the professional education materials, the</p> <p>3 instructions for use, other things that were</p> <p>4 associated with the product.</p> <p>5 BY MR. AYLSTOCK:</p> <p>6 Q. Is it your --</p> <p>7 You would agree with me that a sales</p> <p>8 representative should not be trying to clarify</p> <p>9 instructions provided by a preceptor during surgery</p> <p>10 for the doctor?</p> <p>11 A. A sales representative would be a</p> <p>12 resource to the doctor to answer questions that they</p> <p>13 had as it pertains to the instructions for use or</p> <p>14 information that was previously presented to them</p> <p>15 through professional education.</p> <p>16 Q. Well, they're told and you were told</p> <p>17 as a sales rep that you shouldn't be conveying</p> <p>18 information that's outside the instructions for use.</p> <p>19 Correct?</p> <p>20 A. Yes.</p> <p>21 Q. In other words, if there's a question</p> <p>22 that a doctor has about an issue that came up at the</p> <p>23 training about -- with the preceptor -- strike that.</p> <p>24 Let me start over.</p> <p>25 If there was some question about</p>	<p>1 education.</p> <p>2 Q. Well, if there was some question</p> <p>3 about what the preceptor meant and it wasn't</p> <p>4 otherwise in the professional education materials,</p> <p>5 the IFU, sales reps shouldn't be telling the doc how</p> <p>6 to perform the surgery. Correct?</p> <p>7 A. I would agree with that, if it wasn't</p> <p>8 in the materials.</p> <p>9 Q. Would you agree that it's not up to</p> <p>10 the sales rep to interpret what the preceptor meant</p> <p>11 about certain ways to perform this procedure and</p> <p>12 convey the sales rep's own interpretation of that to</p> <p>13 the physician?</p> <p>14 A. Can you ask that question or rephrase</p> <p>15 that question, please?</p> <p>16 Q. Would you agree with me that if the</p> <p>17 sales rep is called upon to interpret what a</p> <p>18 preceptor meant in part of the professional</p> <p>19 education training, the sales rep should direct that</p> <p>20 question to the doctor, to the preceptor, it's not</p> <p>21 up to the sales rep to interpret what the preceptor</p> <p>22 meant and convey that information to the doctor?</p> <p>23 A. That would be consistent with my</p> <p>24 understanding, yes.</p> <p>25 Q. Would you agree that it's the</p>

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<p>1 function of professional education, not the sales</p> <p>2 reps, to show the doctor the proper implantation</p> <p>3 techniques?</p> <p>4 A. Can I ask you to just repeat the</p> <p>5 question?</p> <p>6 Q. Would you agree with me that when it</p> <p>7 comes to the question of how to properly place the</p> <p>8 mesh, the TVT mesh, for any of the TVT products,</p> <p>9 that it's up to the professional education and</p> <p>10 training materials and the preceptors and the</p> <p>11 physicians to provide that information and the sales</p> <p>12 reps shouldn't be conveying that information?</p> <p>13 A. I would believe -- I would agree that</p> <p>14 the professional education materials, the videos,</p> <p>15 the instructions for use, the CD-ROM, would be the</p> <p>16 source of that type of information. The sales rep</p> <p>17 may also have copies of that information if the</p> <p>18 doctor wanted to see that or misplaced it or wanted</p> <p>19 to make sure they had the most recent version of</p> <p>20 that information.</p> <p>21 Q. Can you describe to the jury what is</p> <p>22 meant in the context of professional education by</p> <p>23 the term "tension-free vaginal tape"?</p> <p>24 A. Tension-free vaginal tape was a</p> <p>25 product that was sold by the company for the</p>	<p>1 action, is there some reason why that shouldn't be</p> <p>2 put in writing?</p> <p>3 A. My understanding is that there's a</p> <p>4 credo hotline that any employee is welcome to call</p> <p>5 should they have any questions about the credo.</p> <p>6 Q. Let me move to strike, because I'm</p> <p>7 not asking about a hotline.</p> <p>8 A. Sure, I'm sorry.</p> <p>9 Q. I'm asking, is there any reason that</p> <p>10 you can think of, as director of professional</p> <p>11 education, why an individual within your company</p> <p>12 would be told don't put credo issues in writing?</p> <p>13 MR. BROWN: Objection.</p> <p>14 THE WITNESS: I can't think of a</p> <p>15 reason as I sit here today.</p> <p>16 BY MR. AYLSTOCK:</p> <p>17 Q. You can't think of any good reason?</p> <p>18 MR. BROWN: Objection.</p> <p>19 THE WITNESS: I can't think of a</p> <p>20 reason why that may or may not have been said.</p> <p>21 BY MR. AYLSTOCK:</p> <p>22 Q. And were you ever part of any</p> <p>23 conversations where that was discussed or --</p> <p>24 A. I don't recall.</p> <p>25 Q. I'll show you Exhibit T-1068 -- 1069</p>
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<p>1 treatment of stress urinary incontinence.</p> <p>2 Q. What's meant by the term "tension</p> <p>3 free"?</p> <p>4 MR. BROWN: Objection.</p> <p>5 THE WITNESS: It's my understanding</p> <p>6 that tension free means that the mesh sling is</p> <p>7 placed in a tension-free nature below the urethra.</p> <p>8 BY MR. AYLSTOCK:</p> <p>9 Q. In other words, there shouldn't be</p> <p>10 any tension on the tape?</p> <p>11 MR. BROWN: Objection.</p> <p>12 THE WITNESS: It's my understanding.</p> <p>13 I would defer what degree of tension. I can define</p> <p>14 as I sit here today what tension free means. I</p> <p>15 would defer that to a medical doctor to elaborate on</p> <p>16 what degree of tension is required for a particular</p> <p>17 patient or a particular procedure.</p> <p>18 BY MR. AYLSTOCK:</p> <p>19 Q. Have you ever heard it discussed that</p> <p>20 individuals within your company shouldn't put any</p> <p>21 credo-type issues in writing?</p> <p>22 A. No, I haven't heard that.</p> <p>23 Q. Would there be a reason not -- if</p> <p>24 somebody had an issue that they thought was</p> <p>25 inconsistent with the credo or some course of</p>	<p>1 rather. 1062.</p> <p>2 - - -</p> <p>3 (Deposition Exhibit No. T-1063,</p> <p>4 E-mail chain, top one dated 16 Sep 2004,</p> <p>5 Bates stamped ETH.MESH.00864503 through</p> <p>6 ETH.MESH.00864507, was marked for</p> <p>7 identification.)</p> <p>8 - - -</p> <p>9 BY MR. AYLSTOCK:</p> <p>10 Q. I'm just going to start from the very</p> <p>11 back and just walk through it, so let me know when</p> <p>12 you're ready.</p> <p>13 A. Okay. Thank you.</p> <p>14 Q. Why don't we go through it.</p> <p>15 MR. BROWN: Why don't you see which</p> <p>16 questions --</p> <p>17 MR. AYLSTOCK: I mean --</p> <p>18 MR. BROWN: Well, why don't you see</p> <p>19 which questions you've got and if you need to</p> <p>20 read --</p> <p>21 MR. AYLSTOCK: I don't want to take</p> <p>22 up the time with reading it.</p> <p>23 MR. BROWN: Are you almost through or</p> <p>24 do you --</p> <p>25 THE WITNESS: I'm almost through,</p>

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<p style="text-align: right;">Page 446</p> <p>1 yeah. It's just quite a long chain of e-mails</p> <p>2 that --</p> <p>3 MR. BROWN: Are you asking about all</p> <p>4 of them, Mr. Aylstock?</p> <p>5 MR. AYLSTOCK: I'm just going to walk</p> <p>6 through it. I'm not trying to play games with you</p> <p>7 and ask you stuff where you don't have time to look</p> <p>8 at it. I just -- we've spent five minutes just</p> <p>9 looking at this.</p> <p>10 MR. BROWN: Why don't you go ahead</p> <p>11 and take questions on it. If you need to look at</p> <p>12 other things, you can.</p> <p>13 THE WITNESS: Sure. Absolutely.</p> <p>14 BY MR. AYLSTOCK:</p> <p>15 Q. So it starts September 2004. Right?</p> <p>16 And you're copied on an e-mail from Paul Capponi.</p> <p>17 In fact, he sends it to you, among</p> <p>18 others. Correct?</p> <p>19 A. I believe I was copied on it, yes.</p> <p>20 Q. And that was in your position as</p> <p>21 product director for the TVT-O. Right?</p> <p>22 A. I believe so, yes.</p> <p>23 Q. In other words, you are the person in</p> <p>24 charge of marketing for the TVT-O sling product made</p> <p>25 by Ethicon and J&J. Right?</p>	<p style="text-align: right;">Page 448</p> <p>1 Q. Shannon Campbell is a sales rep?</p> <p>2 A. I believe so, yes.</p> <p>3 Q. So she then responds and copies you,</p> <p>4 among others, about some certain action items</p> <p>5 involving the TVT-O product. Right?</p> <p>6 A. Yes.</p> <p>7 Q. And she talks about one thought</p> <p>8 leader that she recently lost to Monarc,</p> <p>9 Dr. Feagins. Right?</p> <p>10 A. Yes.</p> <p>11 Q. And Monarc is a competitor sling</p> <p>12 using the transobturator approach. Correct?</p> <p>13 A. Yes.</p> <p>14 Q. And you know as product director that</p> <p>15 Monarc was on the market before the TVT-O was on the</p> <p>16 market. Correct?</p> <p>17 A. Yes.</p> <p>18 Q. In fact, that was one of the primary</p> <p>19 reasons why the TVT Classic was losing market share.</p> <p>20 Correct?</p> <p>21 A. Yes, I believe so.</p> <p>22 Q. So to stop that loss of market share,</p> <p>23 Ethicon developed the TVT-O product, correct, to</p> <p>24 compete with the Monarc as a transobturator approach</p> <p>25 to a sling. Correct?</p>
<p style="text-align: right;">Page 447</p> <p>1 A. I believe so at that point in time.</p> <p>2 Q. So there's some ongoing TVT-O action</p> <p>3 items.</p> <p>4 In your role as product director,</p> <p>5 were you involved in handling action items involving</p> <p>6 the TVT-O product?</p> <p>7 A. No, I don't remember being involved</p> <p>8 in handling this particular action item.</p> <p>9 Q. No, that wasn't my question.</p> <p>10 Were you generally involved as</p> <p>11 product director in handling certain action items</p> <p>12 for the TVT-O product generally?</p> <p>13 A. I guess that's a broad question. I</p> <p>14 would be involved in handling items as it pertained</p> <p>15 to marketing of the TVT-O at this particular point</p> <p>16 in time, because that was my function and</p> <p>17 responsibility at this particular point in time.</p> <p>18 Q. Part of marketing is marketing</p> <p>19 through sales representatives. Correct?</p> <p>20 A. Yes.</p> <p>21 Q. Okay.</p> <p>22 And you've had a chance to read the</p> <p>23 e-mail responding to Mr. Capponi here by Shannon</p> <p>24 Campbell. Do you see that?</p> <p>25 A. Yes.</p>	<p style="text-align: right;">Page 449</p> <p>1 MR. BROWN: Objection.</p> <p>2 THE WITNESS: It's my understanding</p> <p>3 in the role that I was in in marketing that the</p> <p>4 TVT-O product was not developed in response to the</p> <p>5 Monarc product. It was developed in response to a</p> <p>6 desire from surgeons to have an alternative approach</p> <p>7 utilizing the transobturator method.</p> <p>8 BY MR. AYLSTOCK:</p> <p>9 Q. Well, in your CV, one of the main</p> <p>10 points that you make as product director is that you</p> <p>11 turned around declining market share, declining unit</p> <p>12 sales and a flat revenue to grow. Do you see that?</p> <p>13 A. Yes.</p> <p>14 Q. And part of the reason and way that</p> <p>15 you turned around that declining market share as</p> <p>16 product director was the introduction of the TVT-O</p> <p>17 transobturator product for Ethicon/J&J. Correct?</p> <p>18 A. Yes, that was part of the way.</p> <p>19 Q. Now, the sales rep is talking about</p> <p>20 Dr. Feagins being lost to a competitor. Right?</p> <p>21 A. Yes.</p> <p>22 Q. He's talking about -- or she, rather,</p> <p>23 is talking about her experience in the last few</p> <p>24 weeks in talking to doctors about a modified TVT-O</p> <p>25 trick. Right?</p>

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<p>1 A. There is reference to the Babcock 2 technique. 3 Q. Okay. 4 What's the Babcock technique? 5 A. The Babcock technique was a method 6 used by the inventor of TVT-O to allow for space 7 between the TVT-O tape and the urethra. It was 8 something that we provided through professional 9 education as a video. 10 Q. Okay. 11 Is that in the IFU? 12 MR. BROWN: Objection. 13 THE WITNESS: I don't think the words 14 "the Babcock technique" are in the IFU, but its 15 intent is included in the IFU, which is to have 16 tension-free placement of the mesh below the 17 urethra. 18 BY MR. AYLSTOCK: 19 Q. So the answer is no, it's not 20 described as such in the IFU? 21 MR. BROWN: Objection. 22 THE WITNESS: The words "Babcock 23 technique" are not in the IFU to my knowledge. 24 BY MR. AYLSTOCK: 25 Q. All right.</p>	<p>1 this particular representative. 2 BY MR. AYLSTOCK: 3 Q. Well, you were copied on this as 4 product director. Right? 5 A. In 2004, I was copied on this, along 6 with it looks like about ten other people. 7 Q. Well, and you knew as product 8 director that sales reps shouldn't be telling 9 doctors how to perform the surgery. Correct? We've 10 already went over that? 11 A. Yes. 12 Q. And what did you do in response to 13 this when you saw this e-mail about the sales rep 14 taking the doctor through the surgery and telling 15 him how to do it? Did you do anything proactively 16 as product director? 17 A. I can't recall as I sit here today. 18 It looks like the response came from Dan Smith, as I 19 read this e-mail. 20 Q. We'll get to that. 21 But you didn't see it -- see fit to 22 respond in any way that you can recall? Because 23 we've looked in your file for any response. We 24 haven't seen it. 25 A. I may have responded by telephone. I</p>
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<p>1 And what Ms. Campbell is saying as 2 the sales rep is, I've "modified the TVT O trick 3 with the babcock for his traditional approach. I 4 had him take the TVT needle, and clamp the tape 5 around it with a babcock like we have talked about 6 with the TVT O." Do you see that? 7 A. Yes. 8 Q. So she's showing this physician how 9 to modify the technique in the operating room. 10 Correct? 11 A. I think this representative is 12 referring to a technique that we made available 13 through professional education. 14 MR. AYLSTOCK: Let me move to strike. 15 That wasn't my question. 16 BY MR. AYLSTOCK: 17 Q. According to this document, she -- it 18 says, "I had him take the TVT needle, and clamp the 19 tape around it." 20 She's directing the physician about 21 how to do the surgery with this TVT-O trick, the 22 Babcock. Right? 23 MR. BROWN: Objection. 24 THE WITNESS: I don't know if that 25 was the intention. I would defer that question to</p>	<p>1 may have responded in some other way than e-mail. 2 Q. Do you have any recollection of 3 responding to this? 4 A. I don't have recollection from 2004 5 of whether I responded to this or not. 6 Q. So Mr. Dan Smith does respond. 7 Right? 8 A. Yes. 9 Q. Is Dan Smith a doctor? 10 A. No. 11 Q. He's an engineer. Right? 12 A. Yes. 13 Q. So he thanks Shannon for the update 14 and says, I've "never heard of" this Babcock "being 15 placed around a" TVT-O "or TVTO needle!" Right? 16 A. Yes. 17 Q. "Where did this come from?" Right? 18 "It is NOT the deLeval technique." Right? 19 A. I agree with that's what it says in 20 this e-mail. 21 Q. Well, and your -- 22 Subsequent to this, you became 23 director of professional education, in charge of 24 ensuring that doctors are properly trained on the 25 TVT-O technique. Right?</p>

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<p>1 A. Subsequent to this, yes.</p> <p>2 Q. So as we sit here today, you, in</p> <p>3 fact, know that what Mr. Smith is saying is correct,</p> <p>4 that it's not part of the de Leval technique and</p> <p>5 it's not part of professional education or the IFU,</p> <p>6 to use a Babcock around the needle?</p> <p>7 A. Yes. I don't think that that's</p> <p>8 consistent with the professional education video on</p> <p>9 the Babcock technique. And I think that's what Dan</p> <p>10 is trying to do is correct that representative's</p> <p>11 understanding of that professional education</p> <p>12 material.</p> <p>13 Q. Because it would be wrong for a sales</p> <p>14 rep to instruct the doctor on how to do the</p> <p>15 technique, particularly if she's instructing the</p> <p>16 doctor to do it in a manner that's inconsistent with</p> <p>17 the IFU or the training provided by your company.</p> <p>18 Correct?</p> <p>19 MR. BROWN: Objection.</p> <p>20 THE WITNESS: I can't say whether</p> <p>21 this particular variation would be of relevance or</p> <p>22 not.</p> <p>23 MR. AYLSTOCK: Move to strike. I'm</p> <p>24 not asking you if it's relevant.</p> <p>25 BY MR. AYLSTOCK:</p>	<p>1 right to finish the question if he needs to.</p> <p>2 BY MR. AYLSTOCK:</p> <p>3 Q. Well, is it -- I want -- you've</p> <p>4 answered my question. So your counsel will have,</p> <p>5 just like you did before, a chance to ask you a lot</p> <p>6 of questions. And I'm trying to get through as much</p> <p>7 as I can today, so I don't need a however unless</p> <p>8 it's directly responsive to my question. And I</p> <p>9 don't think my question was a correct, it's a yes or</p> <p>10 no. And you've answered the question.</p> <p>11 A. I believe that my response is</p> <p>12 directly responsive to your question. And in</p> <p>13 reading this e-mail, it doesn't appear to me that</p> <p>14 this variation would be of significance or</p> <p>15 inconsistent with the professional education</p> <p>16 materials.</p> <p>17 Q. So you believe that even though</p> <p>18 Mr. Smith says that it's not the de Leval technique</p> <p>19 and he's never even heard of it being placed, that</p> <p>20 this would come within the professional education</p> <p>21 for how to perform a TVT-O? Is that your testimony?</p> <p>22 A. I can't testify one way or another.</p> <p>23 This is a communication between a sales</p> <p>24 representative and a member of our R&D department.</p> <p>25 I would defer to them to clarify.</p>
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<p>1 Q. You would agree that it would be</p> <p>2 wrong for this sales rep to provide information to</p> <p>3 the physician that's inconsistent with the IFU or</p> <p>4 the professional education provided by your company.</p> <p>5 Correct?</p> <p>6 A. The under -- my understanding is, and</p> <p>7 again, this e-mail is ten years old. My</p> <p>8 understanding is that the sales representative was</p> <p>9 corrected in their interpretation of the</p> <p>10 professional education materials --</p> <p>11 MR. AYLSTOCK: That wasn't my</p> <p>12 question. Let me move to strike.</p> <p>13 Ann Marie, can you read back my</p> <p>14 question.</p> <p>15 - - -</p> <p>16 (The court reporter read the</p> <p>17 pertinent part of the record.)</p> <p>18 - - -</p> <p>19 THE WITNESS: Yes, the sales</p> <p>20 representative shouldn't provide information that's</p> <p>21 inconsistent with the IFU or the professional</p> <p>22 education materials. However, this particular --</p> <p>23 BY MR. AYLSTOCK:</p> <p>24 Q. No. I'm not asking for however.</p> <p>25 MR. BROWN: Well, he does have a</p>	<p>1 Q. You just told me because you thought</p> <p>2 it was responsive that this wouldn't be inconsistent</p> <p>3 with the professional education.</p> <p>4 You don't know whether it is or it</p> <p>5 isn't as we sit here today, do you? As director of</p> <p>6 professional education, you don't know whether</p> <p>7 placing this Babcock around the needle is consistent</p> <p>8 or inconsistent with the IFU or professional</p> <p>9 education?</p> <p>10 A. I already answered that I believe it</p> <p>11 is consistent with the IFU. The Babcock technique</p> <p>12 video was provided as one of the professional</p> <p>13 education materials.</p> <p>14 Q. So around the needle?</p> <p>15 A. The variation of around the needle I</p> <p>16 would defer to medical affairs or R&D.</p> <p>17 Q. So you don't know whether this</p> <p>18 particular -- the manner in which this particular</p> <p>19 doctor was instructed by this particular sales rep</p> <p>20 is inconsistent or consistent with professional</p> <p>21 education or the IFU, because you don't know whether</p> <p>22 it's consistent to place it around the needle or</p> <p>23 not, don't you?</p> <p>24 A. I don't believe that it --</p> <p>25 MR. BROWN: Paul, just answer his</p>

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<p>1 question.</p> <p>2 THE WITNESS: Sorry.</p> <p>3 MR. BROWN: Which is you either know</p> <p>4 that or you don't know that. That's his question.</p> <p>5 THE WITNESS: I don't know that as I</p> <p>6 sit here today.</p> <p>7 BY MR. AYLSTOCK:</p> <p>8 Q. Well, Mr. Smith certainly didn't</p> <p>9 think it was consistent, did he? Because he says</p> <p>10 it's not the de Leval technique, and de Leval is who</p> <p>11 invented the TVT-O procedure. Right?</p> <p>12 A. It would appear that way.</p> <p>13 Q. So as we sit here today, you have no</p> <p>14 reason to disagree with Mr. Smith and how he</p> <p>15 responded. Correct?</p> <p>16 A. I have no reason as I sit here today</p> <p>17 to disagree with Mr. Smith.</p> <p>18 Q. Now, the sales rep, Ms. Campbell,</p> <p>19 does respond to Mr. Smith. Do you see that?</p> <p>20 A. Yes.</p> <p>21 Q. And she's "been thinking about where</p> <p>22 I received the TVT O babcock idea," and it's from</p> <p>23 several sources. Right?</p> <p>24 A. Where are you reading that?</p> <p>25 Q. The top of the next e-mail in the</p>	<p>1 Q. She wouldn't be calling somebody from</p> <p>2 outside the US? You don't think that happened, do</p> <p>3 you?</p> <p>4 A. I don't know.</p> <p>5 Q. And you were the US product director.</p> <p>6 Right?</p> <p>7 A. I was one of the US product directors</p> <p>8 at this point in time.</p> <p>9 Q. Who were the others --</p> <p>10 A. I don't recall getting a phone call</p> <p>11 from this representative.</p> <p>12 Q. Who were the other product directors</p> <p>13 at this time?</p> <p>14 A. I believe Brian Luscombe was in the</p> <p>15 marketing department.</p> <p>16 Q. He was a product director?</p> <p>17 A. He was a product director.</p> <p>18 Q. Was he on equal par with you or was</p> <p>19 he under you or was he your boss?</p> <p>20 A. There was a period of time that he</p> <p>21 was my boss. I don't know if this was that</p> <p>22 particular period of time.</p> <p>23 Q. Who else was a product director</p> <p>24 during this time?</p> <p>25 A. I believe Giselle Bonet was a product</p>
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<p>1 chain. "Dan, I have been thinking about where I</p> <p>2 received the TVT O babcock idea from and I feel it</p> <p>3 is from several sources." Do you see that?</p> <p>4 A. Yes.</p> <p>5 Q. "I called several reps to see what</p> <p>6 their physicians have been doing" and "I contacted</p> <p>7 the product directors as well." Right?</p> <p>8 A. Yes, I see that it says that.</p> <p>9 Q. And you're the product director at</p> <p>10 this time. Right?</p> <p>11 A. I was one of the product directors at</p> <p>12 this time.</p> <p>13 Q. Okay.</p> <p>14 So were there more than one product</p> <p>15 directors for TVT-O?</p> <p>16 A. I believe so, yes.</p> <p>17 Q. How many were there?</p> <p>18 A. During different time frames, there</p> <p>19 could have been two or three, possibly more.</p> <p>20 Q. Were they divided by region or how</p> <p>21 were the responsibilities allocated?</p> <p>22 A. There was a product director and</p> <p>23 group product director that would have had</p> <p>24 responsibility. There would have been a division in</p> <p>25 responsibilities between the US and outside the US.</p>	<p>1 director.</p> <p>2 Q. Wasn't she foreign or was she US?</p> <p>3 A. She's US.</p> <p>4 Q. Any others you can think of?</p> <p>5 A. Again, this time frame, ten years</p> <p>6 ago, it's hard for me to recall.</p> <p>7 Q. Well, in any event, she called you or</p> <p>8 one of the other product directors according to this</p> <p>9 e-mail and -- in an attempt to figure out where she</p> <p>10 got this TVT-O Babcock idea. Right? That's what</p> <p>11 the e-mail says?</p> <p>12 A. Yes.</p> <p>13 Q. And "some of the ideas were soaking</p> <p>14 the mesh, injecting saline down the sheaths, using a</p> <p>15 hemostat on both sides of the mesh sheath,</p> <p>16 retracting in a lateral position as opposed to</p> <p>17 towards the ceiling, and pulling off one side at a</p> <p>18 time." Do you see that?</p> <p>19 A. I see that, yes.</p> <p>20 Q. As we sit here today, do you know</p> <p>21 whether those are consistent or inconsistent with</p> <p>22 the IFU?</p> <p>23 A. I believe for the most part they're</p> <p>24 consistent with the IFU.</p> <p>25 Q. Well, what's inconsistent with the</p>

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<p>1 IFU?</p> <p>2 A. I don't recall seeing injecting</p> <p>3 saline or soaking the mesh within the IFU.</p> <p>4 Q. Then she says, "I believe" --</p> <p>5 A. Just to clarify, when I say the IFU,</p> <p>6 I'm talking about the professional education</p> <p>7 materials in addition to the IFU.</p> <p>8 Q. So there's nothing in the</p> <p>9 professional education materials or the IFU that</p> <p>10 would suggest that doctors should soak the mesh</p> <p>11 prior to implantation. Correct?</p> <p>12 A. Not that I can recall.</p> <p>13 Q. And same for injecting saline down</p> <p>14 the sheaths. Right?</p> <p>15 A. Not that I can recall.</p> <p>16 Q. Then she says, "I believe it was one</p> <p>17 of Domingo's physicians that was using the deLeval</p> <p>18 technique of using a babcock. This surgeon uses the</p> <p>19 white TVT O needle to create the loop and clamps the</p> <p>20 babcock over it."</p> <p>21 And then she goes on to explain in</p> <p>22 her mind that to her was the de Leval technique</p> <p>23 since she never saw de Leval do it. Right?</p> <p>24 MR. BROWN: Objection.</p> <p>25 THE WITNESS: That's what the e-mail</p>	<p>1 of a reprimand. Right?</p> <p>2 A. No, not necessarily, not from a phone</p> <p>3 call.</p> <p>4 Q. You have a way to formally reprimand</p> <p>5 an employee of yours. Right?</p> <p>6 A. An employee of mine. This</p> <p>7 representative was not an employee of mine.</p> <p>8 Q. Well, you could have went to that</p> <p>9 employee's boss and said, look, she's acting</p> <p>10 inconsistent with the credo and telling this doctor</p> <p>11 how to perform a surgery and I don't think that's</p> <p>12 right and that person should be reprimanded. Right?</p> <p>13 Nothing prevented you from doing that as product</p> <p>14 director?</p> <p>15 A. No, nothing would have permitted me</p> <p>16 from doing that. And I can't --</p> <p>17 Q. You didn't do that, did you?</p> <p>18 A. I can't recall.</p> <p>19 Q. How many people have you reprimanded</p> <p>20 in your career? Do you do that a lot?</p> <p>21 A. I wouldn't say I do it a lot, but I</p> <p>22 would, if I saw incorrect information, I would do my</p> <p>23 best to correct the information as I think this</p> <p>24 e-mail from Dan Smith is trying to do.</p> <p>25 Q. Well, let's see what else she says in</p>
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<p>1 says.</p> <p>2 BY MR. AYLSTOCK:</p> <p>3 Q. "I just extended the same idea with</p> <p>4 the retropubic approach needles" that "the surgeon</p> <p>5 mentioned in" the "prior e-mail that was doing the</p> <p>6 traditional approach." Do you see that?</p> <p>7 A. Yes.</p> <p>8 Q. So she's taking it upon herself to</p> <p>9 extend that idea and tell the doctor to do something</p> <p>10 that's different from the de Leval technique.</p> <p>11 Correct?</p> <p>12 A. It would appear that way for this</p> <p>13 particular e-mail.</p> <p>14 Q. You would agree that would be wrong</p> <p>15 for this rep to be doing that. Right?</p> <p>16 A. As I've said before, the rep should</p> <p>17 be sticking to things that were in the instructions</p> <p>18 for use and the professional education materials.</p> <p>19 Q. And when you saw that she hadn't</p> <p>20 been, did you do anything to reprimand her?</p> <p>21 A. I may have. I can't recall. I may</p> <p>22 have picked up the phone and called this individual.</p> <p>23 I can't recall something from an e-mail from ten</p> <p>24 years ago as I sit here today.</p> <p>25 Q. If you had, there would be a record</p>	<p>1 this e-mail back to Mr. Smith.</p> <p>2 A. I believe the individual's boss is</p> <p>3 copied on this e-mail as well.</p> <p>4 Q. Who is Shannon's boss? Kevin Mahar?</p> <p>5 A. I think it would have been Charles</p> <p>6 Riedley, and Tom Lech is the -- is Charles</p> <p>7 Riedley's -- was Charles Riedley's boss at the time,</p> <p>8 as I can recall as I sit here today.</p> <p>9 Q. So then she goes on and talks about a</p> <p>10 huge challenge. "What is a huge challenge to a rep</p> <p>11 trying to make this right, is that we really don't</p> <p>12 know what the right amount is."</p> <p>13 She's talking about the tension.</p> <p>14 Right?</p> <p>15 MR. BROWN: Objection.</p> <p>16 THE WITNESS: It would appear that</p> <p>17 way from this e-mail.</p> <p>18 BY MR. AYLSTOCK:</p> <p>19 Q. "We know this is a quick fix to the</p> <p>20 problem, but not a clinically backed solution." Do</p> <p>21 you see that?</p> <p>22 A. I do see that, yes.</p> <p>23 Q. "It's almost...trying to decide if a</p> <p>24 8, 10 or 12 millimeter hagar dialator is best for</p> <p>25 tensioning TVT with the patient under general. We</p>

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<p>1 learned the cough test, but relied on surgeons 2 experience with the tensioning under general. The 3 package insert to" the "TVT O reads as follows: 4 'Ensure...the tape is placed with no tension under 5 the urethra.'" Do you see that? 6 A. Yes. 7 Q. You would agree -- 8 Well, when you became director of 9 professional education with responsibilities of the 10 TVT-O product, you became aware that there was 11 issues with how doctors were tensioning the tape. 12 Right? 13 A. No, I don't recall being aware of 14 that. 15 Q. You were aware of it back in 16 September 2004, because you were copied on this 17 e-mail. Right? 18 MR. BROWN: Objection. 19 THE WITNESS: I was copied on this 20 e-mail, yes. 21 BY MR. AYLSTOCK: 22 Q. And you brought that knowledge with 23 you when you became a director of professional 24 education. Right? 25 A. Yes.</p>	<p>1 is; How should we as reps be instructing our 2 physicians to tension the TVT O that aligns with the 3 IFU and fulfills our CREDO responsibility." Right? 4 A. When I finish this question, would it 5 be possible to take a quick bathroom break? 6 Q. Sure, that's fine. 7 A. Thank you. 8 Q. So she's trying to get information 9 out of you and your company and others about how 10 best to instruct physicians on tensioning. Right? 11 That's what the e-mail says? 12 A. Yes, that seems to be what the e-mail 13 says. 14 Q. And to do it in a way that fulfills 15 the credo responsibility. Right? 16 A. Yes. 17 MR. AYLSTOCK: Why don't we take a 18 quick break. 19 THE VIDEOGRAPHER: The time is now 20 2:35. This is the end of Disk Number 3. We are 21 going off the record. 22 - - - 23 (A recess was taken from 2:35 p.m. to 24 2:46 p.m.) 25 - - -</p>
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<p>1 Q. And what did you do -- well, strike 2 that. 3 She goes on to say, "My real question 4 is; How should we as reps be instructing our 5 physicians to tension the TVT O that aligns with the 6 IFU and fulfills our CREDO responsibility?" Do you 7 see that? 8 A. I do, yes. 9 Q. So she's trying to get information 10 from you, Mr. Smith, her boss, Mr. Riedley, and 11 others on how best to instruct physicians for -- on 12 tensioning, because she's trying to fulfill her 13 credo responsibility of putting the patients first. 14 Right? 15 MR. BROWN: Objection. 16 THE WITNESS: I believe that this 17 representative was also talking about the wording 18 from Dr. de Leval's clinical study and referring to 19 the Babcock approach, which was made available 20 through professional education. 21 MR. AYLSTOCK: Let me move to strike, 22 because I didn't -- 23 BY MR. AYLSTOCK: 24 Q. We'll get to all this stuff, but I'm 25 asking you about where she says, "My real question</p>	<p>1 THE VIDEOGRAPHER: The time is now 2 2:46. This is the beginning of Disk Number 4. We 3 are back on the record. 4 BY MR. AYLSTOCK: 5 Q. We're back, Mr. Parisi. 6 Would you agree with me that nobody 7 in Ethicon should ever suggest to a physician to use 8 a surgical technique that differs from that in the 9 IFU surgical technique guide or other professional 10 education materials for any pelvic mesh device? 11 MR. BROWN: Objection. 12 THE WITNESS: I can't answer that 13 question with regard to nobody at Ethicon. I can 14 say from my role in -- with my role in professional 15 education with the company that the information that 16 myself and my group would be responsible for 17 providing would be consistent with the IFU, the 18 surgical technique guide and the professional 19 education materials. 20 MR. AYLSTOCK: Move to strike your 21 answer. 22 BY MR. AYLSTOCK: 23 Q. I'm asking you whether -- and I'll 24 narrow it for you. 25 A. Thank you.</p>

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<p>1 Q. Should anybody at Ethicon</p> <p>2 professional education or in sales, as a sales rep,</p> <p>3 ever suggest to a physician that he or she should</p> <p>4 use a surgical technique that differs from that</p> <p>5 that's in the IFU surgical technique guide or other</p> <p>6 professional education materials for any of your</p> <p>7 pelvic mesh devices?</p> <p>8 A. No.</p> <p>9 Q. Now, back to this e-mail.</p> <p>10 Ms. Shannon is talking about the IFU. Right? Well,</p> <p>11 let me start over.</p> <p>12 We're at the top of page of 505,</p> <p>13 864505, do you see that? Where she's asking, "How</p> <p>14 should" the "reps be instructing our physicians to</p> <p>15 tension the TVT O that aligns with the IFU and</p> <p>16 fulfills our CREDO responsibility?" Are you with</p> <p>17 me?</p> <p>18 A. Yes.</p> <p>19 Q. She then talks about that, "This has</p> <p>20 been such a grey area and everyone seems to have</p> <p>21 their own tensioning technique. With the</p> <p>22 inconsistency of the sheaths, this has only" been</p> <p>23 made -- let me start over.</p> <p>24 She says, "This has been such a grey</p> <p>25 area" that "everyone seems to have their own</p>	<p>1 Q. And --</p> <p>2 But she says, "With the inconsistency</p> <p>3 of the sheaths, this has only made it tougher to</p> <p>4 provide a more uniform response that parallel's the</p> <p>5 IFU." Do you see that?</p> <p>6 A. I do see that, yes.</p> <p>7 Q. And you're copied on this e-mail.</p> <p>8 Right?</p> <p>9 A. Yes.</p> <p>10 Q. So going in as director of</p> <p>11 professional education for the TVT-O product, you</p> <p>12 knew that there had been some question about the</p> <p>13 proper tensioning technique for the TVT-O. Correct?</p> <p>14 A. No.</p> <p>15 Q. Isn't that what you took from this</p> <p>16 e-mail when you read it?</p> <p>17 A. As I read this e-mail, I understand</p> <p>18 that this representative, Shannon Campbell, was</p> <p>19 asking for clarification around the instructions for</p> <p>20 use and the professional education materials.</p> <p>21 As I further read through the</p> <p>22 responses --</p> <p>23 Q. Well, we'll get to the responses.</p> <p>24 Let's take this in stages.</p> <p>25 She wants clarification because she</p>
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<p>1 tensioning technique. With the inconsistency of the</p> <p>2 sheaths, this has only made it tougher to provide a</p> <p>3 more uniform response that parallel's the IFU." Do</p> <p>4 you see that?</p> <p>5 A. I'm sorry, I've lost where you're at.</p> <p>6 Q. At the second full paragraph there.</p> <p>7 A. Okay. Thank you.</p> <p>8 Q. After they're talking about being --</p> <p>9 she's talking about being consistent with the IFU on</p> <p>10 tensioning. Right?</p> <p>11 A. Yes.</p> <p>12 Q. And she says that, "This has been</p> <p>13 such a grey area" that "everyone seems to have their</p> <p>14 own tensioning technique." Right?</p> <p>15 A. That's what it seems to say, yes.</p> <p>16 Q. You would agree with me that it's the</p> <p>17 goal of professional education to provide</p> <p>18 consistency in the implantation techniques for the</p> <p>19 physicians. Right?</p> <p>20 A. Yes.</p> <p>21 Q. You don't want physicians, each</p> <p>22 physician doing their own type of procedure; you</p> <p>23 want the physicians to be consistent with the IFU</p> <p>24 and the prof ed materials. Right?</p> <p>25 A. Yes.</p>	<p>1 believes there's a gray area in the tensioning</p> <p>2 technique. Right?</p> <p>3 A. At that particular point in the</p> <p>4 e-mail chain.</p> <p>5 Q. Right. Okay.</p> <p>6 And so the response from Mr. Smith,</p> <p>7 he has several different responses. Right? He</p> <p>8 says, "Shannon, I am not sure what you're looking</p> <p>9 for, but our mesh will never '...stretch' as</p> <p>10 compared to the Monarc mesh." Right?</p> <p>11 A. I'm sorry, I need to --</p> <p>12 Q. I'm going to Mr. Smith's response to</p> <p>13 Shannon Campbell's statements that there's some</p> <p>14 question about how to tension the tape and it's a</p> <p>15 gray area and she's looking for a little guidance</p> <p>16 consistent with the credo. Right?</p> <p>17 MR. BROWN: Objection.</p> <p>18 THE WITNESS: Can you refer me to the</p> <p>19 section that you're looking at at this point?</p> <p>20 BY MR. AYLSTOCK:</p> <p>21 Q. Well, we just went over Shannon's</p> <p>22 e-mail back to Dan Smith copying you and others, her</p> <p>23 boss and others, about the fact that where she</p> <p>24 received the TVT-O Babcock idea and her belief that</p> <p>25 there was some gray area in how to tension the TVT-O</p>

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<p>1 mesh. Correct?</p> <p>2 A. Yes.</p> <p>3 Q. You see that in the e-mail?</p> <p>4 A. I do.</p> <p>5 Q. Mr. Smith responds to Shannon first</p> <p>6 by saying that, "Our mesh will never '...stretch' as</p> <p>7 compared to Monarc mesh." Right?</p> <p>8 A. I see that, yes.</p> <p>9 MR. BROWN: Objection. Did you say</p> <p>10 never stretch?</p> <p>11 MR. AYLSTOCK: Well, I'm reading the</p> <p>12 e-mail.</p> <p>13 MR. BROWN: It says "will never 'not</p> <p>14 stretch.'" BY MR. AYLSTOCK:</p> <p>15 Q. "Will never 'not stretch' as compared</p> <p>16 to the Monarc mesh." Correct? That's what he says.</p> <p>17 Right?</p> <p>18 A. Yes.</p> <p>19 Q. Then he says, "As for the IFU, it</p> <p>20 also" states "the surgeon needs to 'adjust the</p> <p>21 tape...to avoid positioning the tape with tension."</p> <p>22 Do you see that?</p> <p>23 A. Yes.</p> <p>24 Q. "Many surgeons have different</p> <p>25</p>	<p>1 representative, Shannon Campbell, it's fine to</p> <p>2 suggest to the physician alternative methods of</p> <p>3 sheath removal and implantation. Correct?</p> <p>4 MR. BROWN: Objection.</p> <p>5 THE WITNESS: Yes, that's my</p> <p>6 understanding, reading this e-mail. And that was</p> <p>7 confirmed by regulatory and medical affairs at the</p> <p>8 time.</p> <p>9 BY MR. AYLSTOCK:</p> <p>10 Q. So regulatory and medical affairs</p> <p>11 signed off on the idea of sales reps discussing</p> <p>12 alternative methods of sheath removal and</p> <p>13 implantation with physicians, according to this</p> <p>14 document. Right?</p> <p>15 MR. BROWN: Objection.</p> <p>16 THE WITNESS: According to Dan Smith</p> <p>17 in this document, yes.</p> <p>18 BY MR. AYLSTOCK:</p> <p>19 Q. Ms. Campbell then responds to</p> <p>20 Mr. Smith. Do you see this?</p> <p>21 "As reps, we have quite a</p> <p>22 responsibility and even a great deal of liability."</p> <p>23 Do you see that?</p> <p>24 A. I do, yes.</p> <p>25 Q. As a former sales rep, you know that</p>
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<p>1 techniques as you know and the babcock is just</p> <p>2 another way they can use, if they so choose. I</p> <p>3 don't think" it's "a Credo issue, I would appreciate</p> <p>4 if others would comment on this point." Do you see</p> <p>5 that?</p> <p>6 A. I do, yes.</p> <p>7 Q. Then he goes on and says, "Putting in</p> <p>8 writing or suggesting that their may even be a Credo</p> <p>9 issue is not a good idea!" Right?</p> <p>10 A. I see that, yes.</p> <p>11 Q. And you're copied on this e-mail.</p> <p>12 Right? From Mr. Smith?</p> <p>13 A. From 2004, yes.</p> <p>14 Q. "We have discussed alternative</p> <p>15 methods of sheath removal" in "both Regulatory and</p> <p>16 Medical Affairs and have both said that suggesting</p> <p>17 other methods used by" the "surgeons is not a</p> <p>18 problem." Do you see that?</p> <p>19 A. Yes.</p> <p>20 Q. "This also includes other methods of</p> <p>21 device delivery, since the surgeon ultimately owns</p> <p>22 the responsibility of proper delivery and</p> <p>23 placement." Right?</p> <p>24 A. Yes.</p> <p>25 Q. So Mr. Smith is telling the sales</p>	<p>1 you indeed do have a great deal of responsibility</p> <p>2 when it comes to interacting with the doctors.</p> <p>3 Right?</p> <p>4 A. I believe so, yes.</p> <p>5 Q. And part of that responsibility is</p> <p>6 providing fair and balanced information about the</p> <p>7 risks of the products. Correct?</p> <p>8 A. Yes.</p> <p>9 Q. She then says, "I feel I got a little</p> <p>10 grilled on my suggestion of tensioning, yet there is</p> <p>11 no clear direction on tensioning." Right?</p> <p>12 A. I -- looks like that that's what it</p> <p>13 says, yes.</p> <p>14 Q. "I'm not a rebel looking for my own</p> <p>15 way of doing things. I'm a rep trying to figure out</p> <p>16 what is best from my experiences with surgeons and</p> <p>17 what I see the product doing in the operating room."</p> <p>18 Do you see that?</p> <p>19 A. Yes.</p> <p>20 Q. "My goal is not to get the tape</p> <p>21 changed, yet strive to place the mesh as designed</p> <p>22 without altering it. The surgeon does own</p> <p>23 responsibility for proper delivery and placement."</p> <p>24 Then she says, "The fact is, they," the physicians,</p> <p>25 "look to us as" reps "to show them the proper</p>

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<p style="text-align: right;">Page 478</p> <p>1 placement techniques." Right?</p> <p>2 A. That's what it says, yes.</p> <p>3 Q. You know that as director of</p> <p>4 professional education that doctors sometimes look</p> <p>5 to sales reps to show them proper placement</p> <p>6 techniques. Correct?</p> <p>7 MR. BROWN: Objection.</p> <p>8 THE WITNESS: I wouldn't agree -- I</p> <p>9 can't agree with that.</p> <p>10 BY MR. AYLSTOCK:</p> <p>11 Q. You don't agree with it?</p> <p>12 A. I don't agree with that.</p> <p>13 Q. In fact, it would be wrong for a rep</p> <p>14 to show the doctor proper placement techniques.</p> <p>15 Right?</p> <p>16 A. I would recommend that they utilize</p> <p>17 the professional education materials.</p> <p>18 Q. Because it would be wrong for a sales</p> <p>19 rep to be telling the physician proper placement</p> <p>20 techniques. Correct?</p> <p>21 A. The professional education materials</p> <p>22 would be the source of the correct information.</p> <p>23 Q. So in this instance, if Ms. Campbell</p> <p>24 were, in fact, providing the doctor with placement</p> <p>25 techniques, that would be inconsistent with your</p>	<p style="text-align: right;">Page 480</p> <p>1 or not simple. I would defer that to medical</p> <p>2 affairs.</p> <p>3 BY MR. AYLSTOCK:</p> <p>4 Q. Do you have a set time that's</p> <p>5 required for a physician to sit through the training</p> <p>6 that's -- the professional ed that's provided for</p> <p>7 your company, by your company?</p> <p>8 A. The professional education programs</p> <p>9 are typically a day to a day and a half for these</p> <p>10 types of products in the TVT family.</p> <p>11 Q. I mean, when it comes to implanting a</p> <p>12 medical device, a mesh inside a woman's pelvis</p> <p>13 transvaginally, you would expect that a doctor would</p> <p>14 need a day's worth of training on that before going</p> <p>15 out and starting to operate on women with your</p> <p>16 product; is that right?</p> <p>17 MR. BROWN: Objection.</p> <p>18 THE WITNESS: The doctor would</p> <p>19 receive far more than a day's worth of training.</p> <p>20 They would have completed a residency or a</p> <p>21 fellowship in their specialty, taken the test to</p> <p>22 become board certified. The training that the</p> <p>23 company provides is specific to our product and the</p> <p>24 use of it -- of our product, but certainly they</p> <p>25 would have knowledge beyond the training that we</p>
<p style="text-align: right;">Page 479</p> <p>1 view of professional education. Correct?</p> <p>2 A. Yes.</p> <p>3 Q. And Ethicon's view, as you understand</p> <p>4 it, of professional education. Correct?</p> <p>5 A. Yes.</p> <p>6 Q. Now, you had indicated that it's --</p> <p>7 is it professional education's at Ethicon's desire</p> <p>8 to train only the highly skilled physicians or is it</p> <p>9 their intent to train any ob/gyn that would like to</p> <p>10 do the TVT procedure?</p> <p>11 A. The requirements for the TVT</p> <p>12 procedure would be to train gynecologists,</p> <p>13 urologists or urogynecologists who are board</p> <p>14 certified and are practicing the treatment of stress</p> <p>15 urinary incontinence.</p> <p>16 Q. You would expect, in a procedure like</p> <p>17 this, that physicians be highly skilled in their</p> <p>18 field of practice as a board-certified obstetrician</p> <p>19 or urogynecologist. Right?</p> <p>20 A. Yes.</p> <p>21 Q. And you know that this procedure is</p> <p>22 not a simple procedure, is it?</p> <p>23 MR. BROWN: Objection.</p> <p>24 THE WITNESS: I can't say that I can</p> <p>25 comment on what a physician would term it as simple</p>	<p style="text-align: right;">Page 481</p> <p>1 provided.</p> <p>2 BY MR. AYLSTOCK:</p> <p>3 Q. Of course.</p> <p>4 Because you want them to be highly</p> <p>5 skilled physicians in order to get the product,</p> <p>6 they've got to be board certified and highly</p> <p>7 skilled. Right?</p> <p>8 A. That would be our -- yes. That would</p> <p>9 be our preference, sure.</p> <p>10 Q. Right.</p> <p>11 And your desire is not for a</p> <p>12 physician to spend 45 minutes with a sales rep and</p> <p>13 then start implanting this permanent mesh inside of</p> <p>14 a woman?</p> <p>15 A. If they were treating patients with</p> <p>16 other sling procedures, then it would be possible</p> <p>17 that they would be able to get the information they</p> <p>18 needed to understand the nuances and the differences</p> <p>19 between our product and the technique that they were</p> <p>20 using previously. So that would be the</p> <p>21 clarification of that answer.</p> <p>22 Q. So is there a requirement that in</p> <p>23 order for a physician not to have to undergo the</p> <p>24 full day's worth of training, they need to have been</p> <p>25 proficient in other sling procedures? Is that an</p>

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<p>1 actual requirement of Ethicon or are you just saying</p> <p>2 that?</p> <p>3 MR. BROWN: Objection.</p> <p>4 THE WITNESS: That would be a</p> <p>5 requirement of Ethicon, yes.</p> <p>6 BY MR. AYLSTOCK:</p> <p>7 Q. Okay. Because -- okay. Strike that.</p> <p>8 I'll show you Exhibit 1063.</p> <p>9 - - -</p> <p>10 (Deposition Exhibit No. T-1065,</p> <p>11 E-mail chain, top one dated April 13,</p> <p>12 2005, Bates stamped ETH.MESH.05795322</p> <p>13 through ETH.MESH.05795324, was marked for</p> <p>14 identification.)</p> <p>15 - - -</p> <p>16 BY MR. AYLSTOCK:</p> <p>17 Q. It's an e-mail from Marianne</p> <p>18 Kaminski. We talked about her earlier. Right?</p> <p>19 A. Yes.</p> <p>20 Q. And she's in professional ed. Right?</p> <p>21 A. Yes.</p> <p>22 Q. She e-mails you and a whole bunch of</p> <p>23 other folks?</p> <p>24 A. Yes.</p> <p>25 Q. And the e-mail's talking about "Q1,"</p>	<p>1 that budget for training doctors?</p> <p>2 A. That would be the intent of having</p> <p>3 the budget, but it's possible that training may have</p> <p>4 gone over the budget as this first bullet describes</p> <p>5 here.</p> <p>6 Q. Now, I guess this is a follow-up to</p> <p>7 an earlier e-mail that Marianne sent to you and a</p> <p>8 whole bunch of other folks with this Q1 PE results.</p> <p>9 Do you see that? The next e-mail down, April 13,</p> <p>10 2005.</p> <p>11 A. Okay, thank you.</p> <p>12 It's a little challenging because I</p> <p>13 think we're reading it chronologically backwards,</p> <p>14 but...</p> <p>15 Q. Yeah. Well, there's only two in this</p> <p>16 chain, I think.</p> <p>17 A. There's a memo to Bruno on the last</p> <p>18 page.</p> <p>19 Q. Memo from Bruno?</p> <p>20 A. Memo from Bruno.</p> <p>21 Q. Who's Bruno?</p> <p>22 A. I believe that was Bruno De Lacroix.</p> <p>23 Q. And what was his position?</p> <p>24 A. He was the regional sales director.</p> <p>25 Q. So let's start, then, from the back</p>
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<p>1 I guess first quarter, "PE results - REVISED."</p> <p>2 Was PE professional education</p> <p>3 results?</p> <p>4 A. Yes.</p> <p>5 Q. She's talking about a couple of</p> <p>6 errors in the spreadsheets about TVT costs being</p> <p>7 overstated and some uterine health costs</p> <p>8 understated. Do you see that?</p> <p>9 A. I don't see. Where are you referring</p> <p>10 to?</p> <p>11 Q. Just at the very top there.</p> <p>12 A. At the top of the first page?</p> <p>13 Q. She's talking about a couple of</p> <p>14 errors in the spreadsheet.</p> <p>15 A. Yes, thank you.</p> <p>16 Q. And then the impact on the national</p> <p>17 budget. "TVT is now at 81% of annual budget, not</p> <p>18 108%." Do you see that?</p> <p>19 A. Yes.</p> <p>20 Q. Okay. So --</p> <p>21 And is it fair to say that Ethicon</p> <p>22 has an annual budget for training doctors in</p> <p>23 professional education programs?</p> <p>24 A. Yes.</p> <p>25 Q. And you're expected to stay within</p>	<p>1 with this memo from the regional sales director.</p> <p>2 And he says, "Dear all,</p> <p>3 Congratulations for all the ProfEd activities you</p> <p>4 have done and the ones you have in place." Do you</p> <p>5 see that?</p> <p>6 A. Yes.</p> <p>7 Q. "Special thanks to Paul and Amy who</p> <p>8 have been able to coordinate all that knowing that</p> <p>9 our region suffered at the end of last year for lack</p> <p>10 of" PD -- "PEDM." Did I read that correctly?</p> <p>11 A. I believe so, yes.</p> <p>12 Q. And he's talking about you, right,</p> <p>13 Paul Parisi?</p> <p>14 A. Yes, I believe so.</p> <p>15 Q. Okay.</p> <p>16 So what does that mean, "suffered at</p> <p>17 the end of last year for lack of PEDM"?</p> <p>18 A. I think there was a vacancy in the</p> <p>19 position that I assumed in February of 2005. So</p> <p>20 there was a period that there was not a prof ed</p> <p>21 manager in place. And it appears from this e-mail,</p> <p>22 and I can't recall from 2005, that some -- that Amy</p> <p>23 may have been covering that vacancy during that</p> <p>24 time.</p> <p>25 Q. It looks like you were as well.</p>

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<p>1 Right? Paul and Amy?</p> <p>2 A. Well, I would have assumed</p> <p>3 responsibility for it as of, I believe it was</p> <p>4 February of 2005.</p> <p>5 Q. Okay.</p> <p>6 It says you all -- "You know we are</p> <p>7 all trying to get more funding, right now we do not</p> <p>8 have anything." Right? So prof ed was trying to</p> <p>9 get more funding to train doctors; is that right?</p> <p>10 A. Yes.</p> <p>11 Q. And Ethicon, someone up in the</p> <p>12 corporate, didn't provide it at this point in time.</p> <p>13 Right?</p> <p>14 A. It seems, as I read forward, the</p> <p>15 response was is that there was still budget</p> <p>16 remaining once the numbers were recalculated. There</p> <p>17 were some errors in the spreadsheet that led to the</p> <p>18 previous assumption that there was -- that the</p> <p>19 budget had been overspent, and now it looks like</p> <p>20 Ms. Kaminski is correcting that there was budget</p> <p>21 remaining for both TVT and uterine health.</p> <p>22 MR. AYLSTOCK: Let me move to strike.</p> <p>23 That wasn't my question what happened after that.</p> <p>24 BY MR. AYLSTOCK:</p> <p>25 Q. You know, Mr. Parisi, that</p>	<p>1 Q. Mr. Parisi, you know --</p> <p>2 A. -- the chain of communications.</p> <p>3 Q. Mr. Parisi, you know that at this</p> <p>4 point in time, prof ed was looking for more funding</p> <p>5 to train doctors on these procedures. Correct?</p> <p>6 A. It seems that that's what Bruno was</p> <p>7 trying to communicate.</p> <p>8 Q. I'm asking if you know. You know</p> <p>9 that.</p> <p>10 You're going to sit here and tell the</p> <p>11 jury you don't know that?</p> <p>12 A. I don't know --</p> <p>13 Q. You don't know that?</p> <p>14 A. There's no date on this</p> <p>15 communication.</p> <p>16 Q. I'm not asking about the</p> <p>17 communication.</p> <p>18 MR. BROWN: Answer if you know.</p> <p>19 THE WITNESS: I don't know. I don't</p> <p>20 know.</p> <p>21 BY MR. AYLSTOCK:</p> <p>22 Q. You don't know.</p> <p>23 Was there ever a point in time where</p> <p>24 you tried to get more funding for professional</p> <p>25 education?</p>
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<p>1 professional ed tried to get more funding but it</p> <p>2 wasn't provided to you. Correct?</p> <p>3 A. I don't know that. It seems like the</p> <p>4 response was that it was provided.</p> <p>5 Q. No. What they're talking about is</p> <p>6 whether you're under or over budget.</p> <p>7 There's nothing in here that says you</p> <p>8 got more money, is there?</p> <p>9 A. I think by definition I read this to</p> <p>10 understand that if we're at 81 percent of the annual</p> <p>11 budget, that we still have roughly 20 percent</p> <p>12 remaining to spend.</p> <p>13 MR. AYLSTOCK: Move to strike.</p> <p>14 BY MR. AYLSTOCK:</p> <p>15 Q. My question is how -- whether you're</p> <p>16 over or under budget.</p> <p>17 My question is, you agreed with me</p> <p>18 that prof ed was, including you, were trying to get</p> <p>19 more funding for prof ed. Right? You just agreed</p> <p>20 with me. Are you going to change your testimony</p> <p>21 again?</p> <p>22 MR. BROWN: Objection.</p> <p>23 THE WITNESS: There's not dates on</p> <p>24 all of these e-mails, so it's difficult to follow --</p> <p>25 BY MR. AYLSTOCK:</p>	<p>1 A. It's possible.</p> <p>2 Q. You know it happened. I know it's</p> <p>3 possible, but you know it happened.</p> <p>4 Sit here, look in the camera and tell</p> <p>5 this jury whether you know that it happened or not,</p> <p>6 please.</p> <p>7 MR. BROWN: Objection.</p> <p>8 THE WITNESS: To the degree that I</p> <p>9 can recollect as I sit here today, I believe it was</p> <p>10 possible that professional education would have been</p> <p>11 seeking more funding if there was a need.</p> <p>12 BY MR. AYLSTOCK:</p> <p>13 Q. That wasn't my question.</p> <p>14 A. I think that this --</p> <p>15 Q. Look in the camera and tell this</p> <p>16 jury --</p> <p>17 A. -- e-mail goes on to respond --</p> <p>18 MR. BROWN: I haven't seen the</p> <p>19 document, Bryan, so I can't even --</p> <p>20 MR. AYLSTOCK: I don't even care</p> <p>21 about the document.</p> <p>22 MR. BROWN: -- I don't even know if I</p> <p>23 need to object because I don't know if it's from</p> <p>24 him, if it's not from him. So I'd like to take 30</p> <p>25 seconds.</p>

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<p style="text-align: right;">Page 490</p> <p>1 MR. AYLSTOCK: Take a minute and look 2 at the document, but I'm not even asking about the 3 document right now. 4 BY MR. AYLSTOCK: 5 Q. Mr. Parisi, under oath, tell this 6 jury whether you ever requested more funding, or 7 anyone in your department at professional education, 8 for professional education activities related to the 9 TVT or any other pelvic health product, yes or no? 10 A. Yes, I believe that we did. 11 Q. And in this instance, more funding 12 was not provided, but you were able to remain under 13 budget. Correct? 14 A. No, I don't agree with that. 15 Q. Is it your testimony that more 16 funding was provided in this instance, or do you 17 recall? 18 A. I don't recall -- 19 Q. Okay. 20 A. -- as I sit here today. 21 Q. Thank you. 22 So let's look what Mr. Lacroix, Bruno 23 Lacroix, De Lacroix, had to say to all. He 24 referenced you and the funding. Right? "You know 25 we are all trying to get more funding, right now we</p>	<p style="text-align: right;">Page 492</p> <p>1 hands-on training model. 2 Q. So what he's saying is that we can 3 save money, since we don't have any more funding 4 from the company, and reinforce -- in reinforcing to 5 the reps that they can sit down with these average 6 ob/gyns for 45 minutes and train them. Correct? 7 MR. BROWN: Objection. 8 THE WITNESS: It's my understanding, 9 now that I've had a chance to read the rest of his 10 statement, that he's suggesting that for doctors 11 that had prior experience using sling materials. He 12 goes on to say that if there's a need for an 13 official preceptorship after that, it would -- it 14 would be made available. 15 BY MR. AYLSTOCK: 16 Q. Sir, where does it say that these 17 reps should be spending 45 minutes for those with 18 prior experience? It doesn't say that, does it? 19 A. I don't see those words in the 20 document. 21 Q. In fact, what it says is average. 22 They should train themselves on the TVT-Os, 23 especially the average ob/gyns. Right? That's what 24 it says? 25 A. That is what it says.</p>
<p style="text-align: right;">Page 491</p> <p>1 do not have anything...it is important that we take 2 advantage of that to ask ourselves and our people to 3 improve our processes." Right? That's what he 4 says? 5 A. Yes. 6 Q. In other words, he's saying since we 7 don't have more funding, let's make sure that we're 8 maximizing the dollars that we do have to improve 9 our processes of professional education. Correct? 10 A. Yes. 11 Q. And then he says, if you turn to the 12 next page, "To me the biggest progress we can make 13 is to reinforce the reps in 'training' themselves on 14 TVT-Os." Do you see that? 15 A. Yes. 16 Q. Especially "the 'average' obgyns." 17 Do you see that? 18 A. Yes. 19 Q. "They can sit down with them for 45 20 minutes, go through the procedure (cd rom and 21 leaflets), discuss the anatomy and use a sample" of 22 the "PF model." Do you see that? 23 A. Yes. 24 Q. What's the PF model? 25 A. I believe that's a pelvic floor</p>	<p style="text-align: right;">Page 493</p> <p>1 Q. It doesn't say the highly skilled 2 ob/gyns who have already done other sling 3 procedures, does it? It doesn't say that? 4 A. I don't see those words in here, but 5 I believe that was the intention and spirit of this 6 e-mail. 7 Q. There's nothing in this e-mail that 8 supports your belief, does it? In fact, the e-mail 9 says "'average' obgyns." Correct? 10 MR. BROWN: If he's asking you what's 11 in the e-mail, just answer him yes or no if it's in 12 the e-mail. 13 THE WITNESS: Yes, I don't see that 14 in e-mail. 15 BY MR. AYLSTOCK: 16 Q. In fact, he puts average in quotes. 17 Right? 18 A. Yes. 19 Q. And then he does say -- 20 Well, you would agree with me that if 21 a rep is spending 45 minutes with a doctor and 22 providing them with CD-ROMs and leaflets, that's a 23 cheaper way of training a doctor than an official 24 preceptorship. Right? We looked at a document 25 earlier on those costs, we can pull it out if you</p>

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<p>1 want, but you would agree with me on that. Right?</p> <p>2 A. I would agree with that, yes.</p> <p>3 Q. In fact, the official preceptorship</p> <p>4 we saw in the other document is the most expensive</p> <p>5 way to train doctors. Right?</p> <p>6 A. No, that's not correct.</p> <p>7 Q. The cadaver lab is the most expensive</p> <p>8 way?</p> <p>9 A. I believe so, yes.</p> <p>10 Q. Well, the preceptorship is certainly</p> <p>11 a lot more expensive than a rep sitting down with a</p> <p>12 doctor for 45 minutes and giving them a CD and using</p> <p>13 the model. Right?</p> <p>14 A. I don't know what it costs.</p> <p>15 Q. I didn't ask what you knew if it</p> <p>16 would cost.</p> <p>17 You would agree with me that it's a</p> <p>18 lot more expensive to put a prospective physician</p> <p>19 through a preceptorship than for the rep to sit down</p> <p>20 with the doctor for 45 minutes and hand out a copy</p> <p>21 of a CD and show him on a model how to do it.</p> <p>22 Right?</p> <p>23 A. Yes, I would agree with that.</p> <p>24 Q. "In any case it would help the</p> <p>25 Preceptorship to be more valuable and more</p>	<p>1 the more we will increase our ROI." Do you see</p> <p>2 that?</p> <p>3 A. Yes.</p> <p>4 Q. That's return on investment. Right?</p> <p>5 A. Yes.</p> <p>6 Q. "The more money we will get." Right?</p> <p>7 A. Yes.</p> <p>8 Q. "Logic and discipline, right? Thanks</p> <p>9 for your help." Do you see that?</p> <p>10 A. I do, yes.</p> <p>11 Q. And then your boss, Marianne</p> <p>12 Kaminski, forwards this, along with her analysis of</p> <p>13 the numbers about whether you're over or under</p> <p>14 budget for physician training. Right?</p> <p>15 A. Yes.</p> <p>16 Q. And so you would agree with me that</p> <p>17 in your organization, when it came to physician</p> <p>18 training, there was a focus on return on investment</p> <p>19 and getting more money. Right? According to this</p> <p>20 document?</p> <p>21 MR. BROWN: Objection.</p> <p>22 THE WITNESS: Can you rephrase the</p> <p>23 question, please?</p> <p>24 BY MR. AYLSTOCK:</p> <p>25 Q. Well, you would agree with me that</p>
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<p>1 importantly, it would create a stronger and deeper</p> <p>2 relationship between the doc and the rep." Right?</p> <p>3 Do you see that?</p> <p>4 A. I see that, yes.</p> <p>5 Q. "If the need is to have credential,</p> <p>6 may be a dinner with presentation would be enough (I</p> <p>7 do not know that for sure but...)" do you see that?</p> <p>8 A. Yes, I see that.</p> <p>9 Q. "Be creative!"</p> <p>10 That's what Ms. Kaminski says.</p> <p>11 Right?</p> <p>12 A. It seems to be that this was from</p> <p>13 Mr. De Lacroix.</p> <p>14 Q. Right.</p> <p>15 Ms. Kaminski's name is at the bottom,</p> <p>16 because I guess she was forwarding this e-mail from</p> <p>17 Bruno. Right?</p> <p>18 A. That would appear that way.</p> <p>19 Q. And Kaminski was your boss at the</p> <p>20 time. Right?</p> <p>21 A. Yes.</p> <p>22 Q. It says, indeed she said -- strike</p> <p>23 that.</p> <p>24 Mr. De Lacroix says, "The more we</p> <p>25 improve our ProfEd processes and ways of thinking,</p>	<p>1 when it comes to professional education, one of the</p> <p>2 things that was focused on by your company and your</p> <p>3 department, including your boss, Ms. Kaminski, was</p> <p>4 return on investment and making more money for the</p> <p>5 company. Correct?</p> <p>6 MR. BROWN: Objection.</p> <p>7 THE WITNESS: It's my understanding</p> <p>8 that according to this e-mail that there was</p> <p>9 discussion between Mr. De Lacroix and Ms. Kaminski</p> <p>10 or correspondence between the two of them that</p> <p>11 referred to return on investment, yes.</p> <p>12 BY MR. AYLSTOCK:</p> <p>13 Q. And in fact, you know that</p> <p>14 Mr. De Lacroix's thoughts here were implemented by</p> <p>15 your company in allowing reps to train doctors with</p> <p>16 the CD in order to save money. Correct?</p> <p>17 A. Yes, for doctors that had prior</p> <p>18 experience with similar types of products.</p> <p>19 MR. AYLSTOCK: Move to strike after</p> <p>20 "yes."</p> <p>21 - - -</p> <p>22 (Deposition Exhibit No. T-1064,</p> <p>23 E-mail chain, top one dated 23 Nov 2006,</p> <p>24 Bates stamped ETH.MESH.03921637 through</p> <p>25 ETH.MESH.03921640, was marked for</p>

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<p>1 identification.)</p> <p>2 - - -</p> <p>3 BY MR. AYLSTOCK:</p> <p>4 Q. Let me show you Exhibit 1064.</p> <p>5 Now, this e-mail chain is dated</p> <p>6 November of 2006; is that right?</p> <p>7 A. Yes.</p> <p>8 Q. And you were director of professional</p> <p>9 education during this time period for the TVT</p> <p>10 products including the TVT SECUR and the TVT-O and</p> <p>11 the TVT Classic. Right?</p> <p>12 A. In the US, yes.</p> <p>13 Q. As director of professional</p> <p>14 education, you knew it would be improper for the rep</p> <p>15 to train the doctor on how to do the product -- how</p> <p>16 to do the procedure, either TVT-O or TVT-S or TVT</p> <p>17 Classic or any other one. Right?</p> <p>18 A. That was my understanding, yes.</p> <p>19 Unless the doctor had prior experience using another</p> <p>20 sling material, another TVT-like product.</p> <p>21 Q. So is it your testimony that if they</p> <p>22 had experience, the rep could train the doctor on</p> <p>23 how to use a different TVT product.</p> <p>24 That's not your testimony, is it?</p> <p>25 A. I'm a little confused with this</p>	<p>1 expect to be notified of that as director of</p> <p>2 professional education. Correct?</p> <p>3 A. If the medical director felt that I</p> <p>4 needed to be notified about it, yes, I would expect</p> <p>5 that they would notify me.</p> <p>6 Q. Because professional education's job</p> <p>7 is to make sure that the product is being used</p> <p>8 safely and effectively. You testified to that.</p> <p>9 Right? That was your job?</p> <p>10 A. Yes.</p> <p>11 Q. And if you don't know of issues that</p> <p>12 are coming up with the training of physicians and</p> <p>13 the safe and effective use of the product, you can't</p> <p>14 effectively do your job as director of professional</p> <p>15 education, can you?</p> <p>16 A. Can you rephrase the question,</p> <p>17 please?</p> <p>18 Q. If issues come up in the training of</p> <p>19 physicians on how to safely and effectively use the</p> <p>20 TVT products and you're not made aware of those</p> <p>21 issues, you can't effectively do your job as</p> <p>22 director of professional education, can you?</p> <p>23 MR. BROWN: Objection.</p> <p>24 THE WITNESS: As it relates -- let me</p> <p>25 start that over again.</p>
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<p>1 document, so I'm having a little bit of difficulty</p> <p>2 following your train of questions. This appears to</p> <p>3 be a document that I was not involved in, and it</p> <p>4 appears to be with correspondence between the</p> <p>5 members of the company outside of the United States.</p> <p>6 Q. Well, David Robinson is in this</p> <p>7 country. Right? In fact, he was a medical</p> <p>8 director?</p> <p>9 A. Yes.</p> <p>10 Q. He's someone you interacted with as</p> <p>11 director of professional education. Right?</p> <p>12 A. Yes.</p> <p>13 Q. Let me ask you this.</p> <p>14 When it came to issues of training,</p> <p>15 would it -- would you agree with me that if training</p> <p>16 issues came up on a particular TVT product, in order</p> <p>17 for you to do your job as director of professional</p> <p>18 education, it's incumbent upon other members of the</p> <p>19 team, including medical affairs, to inform you of</p> <p>20 any training issues that need to be corrected.</p> <p>21 You'd agree with that. Right?</p> <p>22 A. Yes.</p> <p>23 Q. In other words, if issues were coming</p> <p>24 up on the implantation of one of these devices that</p> <p>25 could be corrected through training, you would</p>	<p>1 My understanding is that the company</p> <p>2 medical director would inform me as professional</p> <p>3 education of any information that they had as it</p> <p>4 pertained to US professional education as for the</p> <p>5 role that I was in at this particular point in time.</p> <p>6 BY MR. AYLSTOCK:</p> <p>7 Q. Well, if there were issues in the</p> <p>8 training of any of the TVT devices that needed to be</p> <p>9 corrected, you would have expected to have been</p> <p>10 brought into that discussion so that you could make</p> <p>11 corrections to the professional education materials</p> <p>12 and make sure the doctors are properly trained.</p> <p>13 Correct?</p> <p>14 A. If there were issues in the training</p> <p>15 that my group or team was providing, I would expect</p> <p>16 that we would be alerted to that and be allowed to</p> <p>17 make corrections to that. And we did that with all</p> <p>18 diligence. I'm not aware of this particular chain</p> <p>19 of e-mails from different countries outside of the</p> <p>20 US as I sit here today.</p> <p>21 MR. AYLSTOCK: Motion to strike "and</p> <p>22 we did that" forward.</p> <p>23 THE WITNESS: Could I take a short</p> <p>24 break?</p> <p>25 MR. AYLSTOCK: Sure.</p>

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<p>1 THE VIDEOGRAPHER: The time is now</p> <p>2 3:24. We are going off the record.</p> <p>3 - - -</p> <p>4 (A recess was taken from 3:24 p.m. to</p> <p>5 3:37 p.m.)</p> <p>6 - - -</p> <p>7 THE VIDEOGRAPHER: The time is now</p> <p>8 3:37. We are back on the record.</p> <p>9 MR. AYLSTOCK: I need to, for the</p> <p>10 record, correct the last exhibit that was used, the</p> <p>11 e-mail from Marianne Kaminski to Mr. Parisi and</p> <p>12 others should have been Exhibit 1065. It was</p> <p>13 mismarked 1064, so we had two 1064s. So we've</p> <p>14 remarked it 1065. And it was 1063, but there were</p> <p>15 two of them, so we corrected that.</p> <p>16 - - -</p> <p>17 (A discussion off the record</p> <p>18 occurred.)</p> <p>19 - - -</p> <p>20 (Deposition Exhibit No. T-1066, KOL</p> <p>21 Interview: Carl G. Nilsson, Interview:</p> <p>22 06.18.08(10-4pm), Bates stamped</p> <p>23 ETH.MESH.04048515 through</p> <p>24 ETH.MESH.04048520, was marked for</p> <p>25 identification.)</p>	<p>1 experienced negative consequences from it?</p> <p>2 A. As it pertains to TVT SECUR, yes,</p> <p>3 I've heard that. And hands-on training was</p> <p>4 available in the United States for TVT SECUR.</p> <p>5 Q. At what point did it become required</p> <p>6 by Ethicon?</p> <p>7 A. I can't say. I didn't use the word</p> <p>8 "required."</p> <p>9 Q. So even though Ethicon knew that</p> <p>10 hands-on training would be superior for the TVT</p> <p>11 SECUR, it never instituted a requirement for</p> <p>12 hands-on training, did it?</p> <p>13 A. Hands-on training models were</p> <p>14 implemented in the United States for TVT SECUR prior</p> <p>15 to the time frame in this e-mail.</p> <p>16 Q. Well, when you say they were</p> <p>17 implemented, they were offered but they weren't</p> <p>18 required by the company to implant the product.</p> <p>19 Correct?</p> <p>20 A. The company would provide them at all</p> <p>21 of its training programs.</p> <p>22 Q. Listen to my question.</p> <p>23 MR. AYLSTOCK: Move to strike.</p> <p>24 BY MR. AYLSTOCK:</p> <p>25 Q. Because my question was, did the</p>
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<p>1 - - -</p> <p>2 THE VIDEOGRAPHER: The time is now</p> <p>3 3:38. We're going off record.</p> <p>4 - - -</p> <p>5 (A discussion off the record</p> <p>6 occurred.)</p> <p>7 - - -</p> <p>8 THE VIDEOGRAPHER: The time is now</p> <p>9 3:39. We are back on the record.</p> <p>10 BY MR. AYLSTOCK:</p> <p>11 Q. Before we took a short break,</p> <p>12 Mr. Parisi, you had in front of you Exhibit 1064, an</p> <p>13 e-mail from Harel Gadot from November 2006. Do you</p> <p>14 see that?</p> <p>15 A. Yes.</p> <p>16 Q. And this e-mail chain talks about</p> <p>17 that, at least according to Mr. Gadot, that the</p> <p>18 "right training (hands-on) is the difference between</p> <p>19 successful adoption of the product or having some</p> <p>20 negative feedback on it." Do you see that?</p> <p>21 A. I do, yes.</p> <p>22 Q. Have you ever heard that, as director</p> <p>23 of professional education, or in any other capacity</p> <p>24 at Ethicon, that hands-on training would be better</p> <p>25 training for physicians when it comes to a patient's</p>	<p>1 company, did Ethicon or J&J ever require physicians</p> <p>2 to undergo hands-on training for the TVT SECUR</p> <p>3 product in order to sell the product for</p> <p>4 implantation by that physician?</p> <p>5 MR. BROWN: Objection.</p> <p>6 BY MR. AYLSTOCK:</p> <p>7 Q. Yes or no?</p> <p>8 A. I don't recall that being a</p> <p>9 requirement. However, the hands-on training models</p> <p>10 were available if the physician --</p> <p>11 Q. See, I'm going to have to ask it</p> <p>12 again, because I didn't ask about whether they were</p> <p>13 available or not.</p> <p>14 A. Sure.</p> <p>15 Q. I asked whether Ethicon ever required</p> <p>16 doctors to undergo hands-on training before they</p> <p>17 were permitted to implant any of the TVT products?</p> <p>18 MR. BROWN: Objection.</p> <p>19 BY MR. AYLSTOCK:</p> <p>20 Q. Yes or no? Was it ever a</p> <p>21 requirement?</p> <p>22 A. It's difficult for me to answer that</p> <p>23 for any of the TVT products. As it relates to the</p> <p>24 TVT SECUR, hands-on training was available. I can't</p> <p>25 say today as I sit here whether that was made a</p>

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<p>1 requirement or not.</p> <p>2 Q. You don't know?</p> <p>3 A. I don't know.</p> <p>4 Q. And as we sit here today, you're</p> <p>5 still in charge of professional education for TVT</p> <p>6 SECUR? You don't know whether doctors were ever</p> <p>7 required to undergo hands-on training before they</p> <p>8 were allowed to implant it by your company?</p> <p>9 MR. BROWN: Objection.</p> <p>10 BY MR. AYLSTOCK:</p> <p>11 Q. You don't know?</p> <p>12 A. I am currently -- TVT SECUR is no</p> <p>13 longer marketed by our company, so I can't say</p> <p>14 today. I can say in this time period in 2006,</p> <p>15 hands-on training was available for TVT SECUR.</p> <p>16 MR. AYLSTOCK: Move to strike.</p> <p>17 That's not my question.</p> <p>18 BY MR. AYLSTOCK:</p> <p>19 Q. My question is, as we sit here today,</p> <p>20 you have no idea, you don't know whether your</p> <p>21 company ever required hands-on training before it</p> <p>22 would sell the TVT-S for implantation by a doctor.</p> <p>23 Correct?</p> <p>24 MR. BROWN: Objection.</p> <p>25 BY MR. AYLSTOCK:</p>	<p>1 You don't believe there's ever been</p> <p>2 such a requirement?</p> <p>3 A. I can't recall as I sit here today.</p> <p>4 MR. BROWN: Objection.</p> <p>5 BY MR. AYLSTOCK:</p> <p>6 Q. You do recall discussions on the</p> <p>7 TVT-S about the need to do hands-on training to</p> <p>8 ensure doctors implant it correctly and safely for</p> <p>9 the patient?</p> <p>10 A. I recall discussions on hands-on</p> <p>11 training of the TVT-S, and it was something that my</p> <p>12 group made available to physicians in the United</p> <p>13 States.</p> <p>14 Q. But to your knowledge never made a</p> <p>15 requirement?</p> <p>16 MR. BROWN: Objection.</p> <p>17 THE WITNESS: I don't recall it being</p> <p>18 a requirement.</p> <p>19 BY MR. AYLSTOCK:</p> <p>20 Q. Who did you have those discussions</p> <p>21 with about the need for hands-on training?</p> <p>22 A. Medical affairs.</p> <p>23 Q. Who? Do you remember the names?</p> <p>24 A. I can't recall from 2006 at this</p> <p>25 point.</p>
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<p>1 Q. You don't know?</p> <p>2 MR. BROWN: Objection.</p> <p>3 THE WITNESS: Correct.</p> <p>4 BY MR. AYLSTOCK:</p> <p>5 Q. When it came to any of the other TVT</p> <p>6 devices, is that the same answer, you don't know</p> <p>7 whether there was ever a requirement or not?</p> <p>8 A. As I sit here today --</p> <p>9 MR. BROWN: Objection.</p> <p>10 THE WITNESS: -- I would have to</p> <p>11 refer to documents. I can't answer that question.</p> <p>12 BY MR. AYLSTOCK:</p> <p>13 Q. Okay.</p> <p>14 And you're -- currently have a job as</p> <p>15 regional manager for professional education</p> <p>16 overseeing products, including the TVT Classic and</p> <p>17 the TVT-O. Correct?</p> <p>18 A. Yes.</p> <p>19 Q. Is there a requirement that those</p> <p>20 physicians undergo hands-on training today?</p> <p>21 MR. BROWN: Objection.</p> <p>22 THE WITNESS: There's not a</p> <p>23 requirement today, to my understanding.</p> <p>24 BY MR. AYLSTOCK:</p> <p>25 Q. And you don't know --</p>	<p>1 Q. You don't know who the -- who was in</p> <p>2 medical affairs back then? We know David Robinson</p> <p>3 is on that e-mail. Right?</p> <p>4 A. Yes, we know David Robinson is on</p> <p>5 that e-mail.</p> <p>6 Q. And he was medical affairs. Right?</p> <p>7 A. He was in medical affairs at that</p> <p>8 point in time in 2006.</p> <p>9 Q. So does that refresh your</p> <p>10 recollection as to whether Mr. Robinson ever came to</p> <p>11 you and said, Mr. Parisi, we may need to institute</p> <p>12 hands-on training for the TVT-S for the safety of</p> <p>13 the patients?</p> <p>14 A. I don't recall.</p> <p>15 Q. I show you Exhibit T-1066.</p> <p>16 You know who Dr. Nilsson is, don't</p> <p>17 you?</p> <p>18 A. Yes.</p> <p>19 Q. Who is Dr. Nilsson?</p> <p>20 A. Dr. Nilsson is a gynecologist</p> <p>21 practicing in Scandinavia.</p> <p>22 Q. Did you ever meet him?</p> <p>23 A. I believe I have, yes.</p> <p>24 Q. And he's a KOL, that's a key opinion</p> <p>25 leader. Right?</p>

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<p>1 A. Yes.</p> <p>2 Q. One of your jobs was interacting with</p> <p>3 and developing key opinion leaders when it came to</p> <p>4 the use of the TVT products. Right?</p> <p>5 A. Can you repeat the question or</p> <p>6 clarify the question?</p> <p>7 Q. Yeah.</p> <p>8 One of your jobs in your CV talks</p> <p>9 about how you managed 200-plus KOL faculty over the</p> <p>10 past ten years. That's on your CV.</p> <p>11 A. Yes.</p> <p>12 Q. And it also says one of your skills</p> <p>13 is in multicompany experience, regulatory compliance</p> <p>14 expertise and surgeon KOL partnership development.</p> <p>15 That's in your CV. Right?</p> <p>16 A. Yes.</p> <p>17 Q. And by partnership, Ethicon would</p> <p>18 partner with these key opinion leaders to help it</p> <p>19 market the product, the TVT products. Correct?</p> <p>20 A. There's a variety of reasons that</p> <p>21 Ethicon would have partnered with key opinion</p> <p>22 leaders.</p> <p>23 Q. Well, one reason is to market the</p> <p>24 product. You'd agree with that. Right?</p> <p>25 A. When I was in a marketing role, I may</p>	<p>1 Assessment/Anesthesia Discussion." Right?</p> <p>2 A. I'm sorry, where are you looking?</p> <p>3 Q. Where it says, it's the second CN --</p> <p>4 A. Oh, I see it, thank you.</p> <p>5 Q. Do you see that?</p> <p>6 A. "Criticality of Proper" -- that?</p> <p>7 Q. So according to this interview</p> <p>8 transcript in 2008, Dr. Nilsson says that</p> <p>9 learning -- his learning curve was 100 patients</p> <p>10 before he was very good with dry results. Do you</p> <p>11 see that?</p> <p>12 MR. BROWN: Objection.</p> <p>13 THE WITNESS: I do see that -- those</p> <p>14 words on this -- in this document.</p> <p>15 BY MR. AYLSTOCK:</p> <p>16 Q. Well, this isn't the first time</p> <p>17 you've heard that there's a learning curve when it</p> <p>18 comes to physicians implanting the TVT devices.</p> <p>19 Correct? I mean, as director of professional</p> <p>20 education, you know there's a learning curve when it</p> <p>21 comes to doctors implanting your company's products.</p> <p>22 Right?</p> <p>23 A. I would agree with that, yes.</p> <p>24 Q. And for this --</p> <p>25 You would consider Dr. Nilsson a</p>
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<p>1 have interacted with key opinion leaders to market</p> <p>2 the product, yes.</p> <p>3 Q. And you also interact with key</p> <p>4 opinion leaders to be involved with the professional</p> <p>5 education of the product. Right?</p> <p>6 A. Yes.</p> <p>7 Q. You consider it a partnership with</p> <p>8 these key opinion leaders who are in your CV.</p> <p>9 Right?</p> <p>10 A. Yes.</p> <p>11 Q. So Dr. Nilsson is one of the key</p> <p>12 opinion leaders that you partnered with for the TVT</p> <p>13 products. Correct?</p> <p>14 A. I don't recall personally partnering</p> <p>15 with Dr. Nilsson.</p> <p>16 Q. Well, your company did. Right?</p> <p>17 A. It would appear that way, yes.</p> <p>18 Q. And if you'll turn with me to the</p> <p>19 third page, there's some -- there's a nomenclature</p> <p>20 CN for Carl G. Nilsson. Do you see that? These are</p> <p>21 comments by Dr. Nilsson during this KOL interview?</p> <p>22 A. Yes, I see that.</p> <p>23 Q. Is that fair?</p> <p>24 And on the third page, the second</p> <p>25 comment is "Criticality of Proper</p>	<p>1 highly skilled surgeon?</p> <p>2 A. Yes.</p> <p>3 Q. He's one of the key opinion leaders</p> <p>4 in the world on this. Right?</p> <p>5 A. I believe so, yes.</p> <p>6 Q. And for him, it took him about 100</p> <p>7 patients before he was very good with dry results,</p> <p>8 according to this interview. Right?</p> <p>9 MR. BROWN: Objection.</p> <p>10 THE WITNESS: According to -- I see</p> <p>11 those words on this page, yes.</p> <p>12 BY MR. AYLSTOCK:</p> <p>13 Q. And as director of professional</p> <p>14 education, that's not surprising to you, that</p> <p>15 there's a learning curve. Right? You know that to</p> <p>16 be true?</p> <p>17 A. It's not surprising to me, no.</p> <p>18 Q. And it's not surprising that for even</p> <p>19 highly skilled surgeons, it can take up to 100</p> <p>20 surgeries before a surgeon's very good with them</p> <p>21 with dry results?</p> <p>22 MR. BROWN: Objection.</p> <p>23 THE WITNESS: I would defer that to</p> <p>24 medical affairs. This is the first time I'm seeing</p> <p>25 this document.</p>

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<p>1 BY MR. AYLSTOCK:</p> <p>2 Q. Right.</p> <p>3 But as director of professional</p> <p>4 education, you interact and partner with these KOLs</p> <p>5 on a regular basis. Right?</p> <p>6 A. During this time period, I was not</p> <p>7 working for this division of Johnson & Johnson.</p> <p>8 Q. Well, from --</p> <p>9 In your resume, it says you managed</p> <p>10 over 200-plus KOL faculty over the past ten years.</p> <p>11 So I'm asking, in your experience at Ethicon for</p> <p>12 professional education, you know that it takes even</p> <p>13 highly skilled doctors up to 100 surgeries to be</p> <p>14 proficient at implanting the TVT devices. Correct?</p> <p>15 A. No, I can't agree with that.</p> <p>16 Q. This is the first time you've ever</p> <p>17 heard that it might take up to 100 surgeries?</p> <p>18 A. Yes.</p> <p>19 Q. That's all news to you?</p> <p>20 A. I have not heard that degree of</p> <p>21 number of patients.</p> <p>22 Q. And nobody took it upon themselves to</p> <p>23 share this information with you, the director of</p> <p>24 professional education, on the learning curve for</p> <p>25 the devices that you oversaw?</p>	<p>1 You were director of professional</p> <p>2 education at that point in time. Correct?</p> <p>3 - - -</p> <p>4 (Deposition Exhibit No. T-1067,</p> <p>5 Minutes TVT Secur resolution team, First</p> <p>6 meeting 1/22/07, Bates stamped</p> <p>7 ETH.MESH.00528184 and ETH.MESH.00528185,</p> <p>8 was marked for identification.)</p> <p>9 - - -</p> <p>10 BY MR. AYLSTOCK:</p> <p>11 Q. January 2007?</p> <p>12 A. Yes.</p> <p>13 Q. Director of professional education,</p> <p>14 you've been in that position since 2005. Right? So</p> <p>15 you've been in that position a couple of years at</p> <p>16 this point in time, approximately?</p> <p>17 A. Approximately.</p> <p>18 Q. And before that, you were</p> <p>19 professional education manager. Right?</p> <p>20 A. Yes.</p> <p>21 Q. So there's some attendees to this TVT</p> <p>22 SECUR resolution team.</p> <p>23 Have you ever heard of that, that</p> <p>24 there was a resolution team for the TVT SECUR?</p> <p>25 A. Could I have a moment to read the</p>
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<p>1 MR. BROWN: Objection.</p> <p>2 THE WITNESS: I was working for</p> <p>3 another division of Johnson & Johnson in June of</p> <p>4 2008 when this document was produced, so I don't</p> <p>5 recall seeing this document previously.</p> <p>6 BY MR. AYLSTOCK:</p> <p>7 Q. Right. And --</p> <p>8 But if you set aside the document for</p> <p>9 a minute, when you came back as director of</p> <p>10 professional education in October of 2010, I take it</p> <p>11 you got back up to speed on what was happening with</p> <p>12 professional education and out in the field with</p> <p>13 these KOLs and other implanters with the TVT</p> <p>14 products. Right?</p> <p>15 A. I did my best to do that.</p> <p>16 Q. Okay.</p> <p>17 A. But I didn't discuss this particular</p> <p>18 case with Dr. Nilsson.</p> <p>19 Q. Well, you did discuss the fact that</p> <p>20 there was a --</p> <p>21 A. Two-and-a-half years prior.</p> <p>22 Q. Well, you know, in fact, there's --</p> <p>23 I'll rephrase.</p> <p>24 Let me show you this document,</p> <p>25 Exhibit 1067, from January 22, 2007.</p>	<p>1 document?</p> <p>2 Q. Sure.</p> <p>3 Okay. Are you ready?</p> <p>4 A. Yes, I am. Thank you.</p> <p>5 Q. So David Robinson is an attendee.</p> <p>6 And Kevin Mahar, is he in sales and</p> <p>7 marketing?</p> <p>8 A. I believe he was in marketing.</p> <p>9 Q. So we've got the medical affairs, the</p> <p>10 marketing folks.</p> <p>11 Is there anybody on this from</p> <p>12 professional education?</p> <p>13 A. I don't see anyone listed here, no.</p> <p>14 Q. But there's this resolution team, and</p> <p>15 to set the context, it says, there's a "learning</p> <p>16 curve for Secur" that "appears more complex and</p> <p>17 longer than originally expected." Do you see that?</p> <p>18 A. I do, yes.</p> <p>19 Q. Now, as director of professional</p> <p>20 education, when did you become aware that the</p> <p>21 learning curve for SECUR was more complex and longer</p> <p>22 than originally expected?</p> <p>23 A. I believe -- my recollection of this</p> <p>24 is that they're describing some situations that were</p> <p>25 happening in Europe.</p>

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<p>1 Q. Yeah.</p> <p>2 A. And a team was put in place to take</p> <p>3 corrective action against that.</p> <p>4 MR. AYLSTOCK: Move to strike. It</p> <p>5 wasn't my question.</p> <p>6 BY MR. AYLSTOCK:</p> <p>7 Q. When did you become aware, as</p> <p>8 director of professional education, that the</p> <p>9 learning curve for SECUR was more complex and longer</p> <p>10 than was originally expected? Was that fact ever</p> <p>11 brought to your attention?</p> <p>12 A. I may have -- yes, I may have heard</p> <p>13 that.</p> <p>14 Q. And what did your company do to</p> <p>15 remedy that?</p> <p>16 A. The steps that I can recall as I sit</p> <p>17 here today is that a revised procedure document was</p> <p>18 put together that described the surgical technique,</p> <p>19 and that was made available through professional</p> <p>20 education.</p> <p>21 Q. And when did that revised technique</p> <p>22 guide go into effect?</p> <p>23 A. I don't have those dates as I sit</p> <p>24 here today.</p> <p>25 Q. Was that the TVT SECUR procedural</p>	<p>1 BY MR. AYLSTOCK:</p> <p>2 Q. Well, it shouldn't have taken three</p> <p>3 years, if it did take three years, to implement the</p> <p>4 new procedure guide. Correct?</p> <p>5 A. I can't say that it took three years,</p> <p>6 because that's not my recollection of the situation.</p> <p>7 Q. Well, if it did, then something went</p> <p>8 wrong at your company. Right?</p> <p>9 MR. BROWN: Objection.</p> <p>10 BY MR. AYLSTOCK:</p> <p>11 Q. Did you answer that question?</p> <p>12 A. I'm sorry, can you repeat the</p> <p>13 question?</p> <p>14 Q. If it took you three years to change</p> <p>15 it, based upon this knowledge, then something went</p> <p>16 wrong with the professional education at your</p> <p>17 company. Correct?</p> <p>18 MR. BROWN: Objection to form.</p> <p>19 THE WITNESS: I can't answer that</p> <p>20 with a yes or no.</p> <p>21 My understanding is that there --</p> <p>22 BY MR. AYLSTOCK:</p> <p>23 Q. If you can't answer it, that's fine.</p> <p>24 A. I can't answer it. Thank you.</p> <p>25 Q. I'll show you the next exhibit.</p>
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<p>1 steps?</p> <p>2 A. I believe so, yes.</p> <p>3 Q. Would it surprise you that that went</p> <p>4 into effect three years later in 2010?</p> <p>5 A. I'd have to see the documents, so I</p> <p>6 can't comment as to --</p> <p>7 Q. Should it take three years or does it</p> <p>8 take three years to implement a new procedure guide</p> <p>9 when safety issues come up and women are getting</p> <p>10 hurt from the poor implantation of the device?</p> <p>11 MR. BROWN: Objection.</p> <p>12 THE WITNESS: It's not my</p> <p>13 understanding that that document was implemented in</p> <p>14 2010.</p> <p>15 BY MR. AYLSTOCK:</p> <p>16 Q. That would surprise you if that were</p> <p>17 true?</p> <p>18 MR. BROWN: Objection.</p> <p>19 BY MR. AYLSTOCK:</p> <p>20 Q. It would surprise you if it took</p> <p>21 three years to do that, wouldn't it?</p> <p>22 MR. BROWN: Objection.</p> <p>23 THE WITNESS: There were documents to</p> <p>24 my recollection that were implemented before that in</p> <p>25 the US.</p>	<p>1 - - -</p> <p>2 (Deposition Exhibit No. T-1068,</p> <p>3 E-mail dated 30 Apr 2007, Bates stamped</p> <p>4 ETH.MESH.00069114, was marked for</p> <p>5 identification.)</p> <p>6 - - -</p> <p>7 BY MR. AYLSTOCK:</p> <p>8 Q. 1068. It's an e-mail from Robert De</p> <p>9 Filippo to you, among others, dated April 2007. Do</p> <p>10 you see that?</p> <p>11 A. Yes.</p> <p>12 Q. And he's e-mailing Dr. Robinson.</p> <p>13 Who is Robert De Filippo?</p> <p>14 A. He's a sales representative.</p> <p>15 Q. He says, "Hello Dr. Robinson, It was</p> <p>16 a pleasure seeing you last week in Florida." Do you</p> <p>17 see that?</p> <p>18 A. Yes.</p> <p>19 Q. "As we discussed, Dr. Mokrzycki and</p> <p>20 Dr. Hatangadi" --</p> <p>21 MR. BROWN: Hatangadi.</p> <p>22 MR. AYLSTOCK: Hatangadi. Let me</p> <p>23 start over.</p> <p>24 BY MR. AYLSTOCK:</p> <p>25 Q. "As we discussed, Dr. Mokrzycki and</p>

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<p>1 Hatangadi have not yet adopted TVT Secur as" a</p> <p>2 "standard of care in treating SUI. Due to some</p> <p>3 early disappointments in their first 50 cases, they</p> <p>4 have encountered some frustrations that" have</p> <p>5 "caused them to back away from Secur." Do you see</p> <p>6 that?</p> <p>7 A. Yes.</p> <p>8 Q. So you were told in April of 2007</p> <p>9 that these physicians, in their first 50 cases, had</p> <p>10 some problems with the TVT SECUR. Right?</p> <p>11 A. I see the word "disappointments"</p> <p>12 used.</p> <p>13 Q. Okay.</p> <p>14 Well, he then says, "I'd like to"</p> <p>15 take "them out to dinner with you and Dan locally in</p> <p>16 New Brunswick so that...both" of you "can share some</p> <p>17 pearls and quite possibly observe...them" doing "3-5</p> <p>18 cases. Additionally, it appears if we...resolve</p> <p>19 some internal issues with St. Peters Hospital which</p> <p>20 will allow them both to begin preceptorships. Since</p> <p>21 I would like...to teach TVT Secur, I would need them</p> <p>22 to have confidence in its efficacy in order to teach</p> <p>23 other physicians." Do you see that?</p> <p>24 A. Yes.</p> <p>25 Q. So this sales rep is telling the</p>	<p>1 BY MR. AYLSTOCK:</p> <p>2 Q. All right. Is it --</p> <p>3 He doesn't say he would like them to</p> <p>4 teach TVT SECUR? He doesn't say that?</p> <p>5 A. My interpretation in reading this</p> <p>6 e-mail is that he's asking our medical director to</p> <p>7 come and spend time with two doctors that had some</p> <p>8 early disappointment with TVT SECUR. He's asking</p> <p>9 them to come into their operating room and observe</p> <p>10 them doing cases and provide any insight or feedback</p> <p>11 that he could in order to give them a better</p> <p>12 understanding of the use of the product.</p> <p>13 Q. And then he says, "if we will resolve</p> <p>14 some internal issues with St. Peters Hospital which</p> <p>15 will allow them both to begin preceptorships."</p> <p>16 Right? I guess, were you aware of some internal</p> <p>17 issues that prohibited these two doctors from being</p> <p>18 preceptors for your company?</p> <p>19 A. No, I wasn't aware of that.</p> <p>20 Q. Well, that's what this e-mail says.</p> <p>21 Apparently there was. Right?</p> <p>22 MR. BROWN: Objection.</p> <p>23 THE WITNESS: That's what</p> <p>24 Mr. De Filippo is saying.</p> <p>25 BY MR. AYLSTOCK:</p>
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<p>1 medical director for your company and you and others</p> <p>2 that he would like to teach them the TVT SECUR</p> <p>3 procedure. Correct?</p> <p>4 A. No.</p> <p>5 Q. That's what he says?</p> <p>6 A. I don't see that.</p> <p>7 Q. Is that what it says?</p> <p>8 A. No. The words that I'm reading on</p> <p>9 here --</p> <p>10 Q. It says -- does it say, "Since I</p> <p>11 would like...to teach" them -- let me strike that.</p> <p>12 It says, "Since I would like them to</p> <p>13 teach TVT Secur." Right?</p> <p>14 A. Yes.</p> <p>15 Q. So even though they're having</p> <p>16 disappointments in their first 50 cases, encountered</p> <p>17 frustrations and are backing away from SECUR, this</p> <p>18 sales rep is trying to get these same doctors to</p> <p>19 teach TVT SECUR. Correct?</p> <p>20 MR. BROWN: Objection.</p> <p>21 BY MR. AYLSTOCK:</p> <p>22 Q. As a preceptorship. Right?</p> <p>23 MR. BROWN: Objection.</p> <p>24 THE WITNESS: No, I don't believe</p> <p>25 that that's what this says.</p>	<p>1 Q. And he wants that resolved so that he</p> <p>2 can get these two doctors to be preceptors to teach</p> <p>3 TVT SECUR. Right?</p> <p>4 MR. BROWN: Objection.</p> <p>5 THE WITNESS: I believe that that --</p> <p>6 this is what -- that is the -- that's my</p> <p>7 interpretation in reading this e-mail, yes.</p> <p>8 BY MR. AYLSTOCK:</p> <p>9 Q. Because doctors that become</p> <p>10 preceptors can make a lot of money. Correct?</p> <p>11 MR. BROWN: Objection.</p> <p>12 THE WITNESS: No, I wouldn't agree to</p> <p>13 that.</p> <p>14 BY MR. AYLSTOCK:</p> <p>15 Q. How much has your company paid</p> <p>16 Dr. Lucente, one of your top preceptors? Over a</p> <p>17 million dollars. Right? I mean, you know that?</p> <p>18 A. Yeah, I would agree with that over a</p> <p>19 period of probably 17 years.</p> <p>20 Q. And you teach --</p> <p>21 When a preceptor is hired, you pay</p> <p>22 them per day. Right?</p> <p>23 A. We pay them per hour, yes.</p> <p>24 Q. Okay.</p> <p>25 So this sales rep is copying you,</p>

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<p>1 among others, to say, even though these doctors are</p> <p>2 having problems with SECUR and they haven't been</p> <p>3 able to resolve them in their first 50 cases, we'd</p> <p>4 like your help in working out this issue so that we</p> <p>5 can make them preceptors teaching the procedure.</p> <p>6 Right?</p> <p>7 A. I think the first thing that he's</p> <p>8 asking for is for the medical director to come and</p> <p>9 work with them in the operating room. And he goes</p> <p>10 on to say, if they -- my understanding is that if</p> <p>11 they were to resolve their issues and have a better</p> <p>12 understanding of the product, Mr. De Filippo's</p> <p>13 desire is that they would potentially become</p> <p>14 preceptors, should there be a need for that to</p> <p>15 happen.</p> <p>16 Q. At least for these --</p> <p>17 You know these two doctors are highly</p> <p>18 skilled surgeons. Right?</p> <p>19 A. Yes.</p> <p>20 Q. And in their first 50 cases, they</p> <p>21 encountered some frustrations that caused them to</p> <p>22 back away from SECUR. Right?</p> <p>23 A. Yes.</p> <p>24 Q. So for them, you knew that the</p> <p>25 learning curve was apparently more than 50 cases,</p>	<p>1 about this, but our position is --</p> <p>2 - - -</p> <p>3 (A discussion off the record</p> <p>4 occurred.)</p> <p>5 - - -</p> <p>6 MR. BROWN: I was saying, Bryan, you</p> <p>7 and I had spoken about this earlier, but our</p> <p>8 position is going to be that the deposition should</p> <p>9 be closed after these two days.</p> <p>10 MR. AYLSTOCK: We obviously disagree</p> <p>11 with that. We haven't covered anywhere close to</p> <p>12 what we need to cover with Mr. Parisi during his</p> <p>13 time.</p> <p>14 MR. SLATER: Just on behalf of New</p> <p>15 Jersey, we haven't gotten to ask Mr. Parisi any</p> <p>16 questioning, any substantive questioning as a</p> <p>17 corporate rep on the TVT devices, other than a few</p> <p>18 scattered questions. We obviously have a great deal</p> <p>19 to ask him, too, we haven't had a chance yet. So we</p> <p>20 obviously will be intending to question Mr. Parisi</p> <p>21 as well on all the other devices that we haven't,</p> <p>22 TVT devices, in fact, the Prosima device, which has</p> <p>23 been neglected quite a bit, but we'll get some light</p> <p>24 shined on it some day soon.</p> <p>25 MR. BROWN: We formally object, but I</p>
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<p>1 because they're still having problems. Right?</p> <p>2 MR. BROWN: Objection.</p> <p>3 THE WITNESS: I could interpret that</p> <p>4 from this particular e-mail as I sit here today.</p> <p>5 BY MR. AYLSTOCK:</p> <p>6 Q. And you were copied back in 2007, so</p> <p>7 you knew that these two highly skilled doctors, at</p> <p>8 least for them, the learning curve was somewhere in</p> <p>9 excess of 50 cases. Right?</p> <p>10 MR. BROWN: Objection.</p> <p>11 THE WITNESS: I agree that that's</p> <p>12 what this document says, and that was</p> <p>13 Mr. De Filippo's opinion.</p> <p>14 BY MR. AYLSTOCK:</p> <p>15 Q. And you knew that as director of</p> <p>16 professional education back in 2007. Correct?</p> <p>17 MR. BROWN: Objection.</p> <p>18 THE WITNESS: Yes.</p> <p>19 MR. AYLSTOCK: I think we'll be done</p> <p>20 for the day.</p> <p>21 THE VIDEOGRAPHER: The time is 4:05.</p> <p>22 This is the end of Disk Number 4. We are adjourning</p> <p>23 the deposition for the day. We are now off the</p> <p>24 record.</p> <p>25 MR. BROWN: You and I have talked</p>	<p>1 understand your position.</p> <p>2 (Deposition adjourned at</p> <p>3 approximately 4:05 p.m.)</p> <p>4</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>

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